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CLOSED CYCLE MARICULTURE AND THE FOOD, DRUG, AND COSMETIC ACT*

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I. INTRODUCTION

In 1960, oyster landings in the Delaware Bay were valued at less than \$40,000, nearly a hundred-fold decrease since the 1950's. Heavy silting and pollution, followed by an epidemic oyster disease, ravaged the oyster beds and provided the impetus for the development of a fledgling industry known as mariculture. Manipulation of the natural environment, such as planting oyster seeds in bays, has gone on for many years, but the type of problem which destroyed the oyster industry in Delaware Bay called for a solution whereby the animals could be grown in a totally enclosed artificial environment where they would not suffer exposure to pollution, disease, siltation, or competing demands for their sensitive natural environment. Closed cycle mariculture on a commercial scale offers the possibilities of year-round production at reliable output rates, uniform product size and quality, a higher meat-to-shell ratio, and animals which are free of disease and parasites. In addition, oysters which take 36 months to mature in natural sea beds can attain adult size in 36 weeks in a properly functioning closed cycle mariculture facility.¹

This article will discuss the applicability of the Federal Food,

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1. A more complete, nontechnical description of a closed cycle mariculture facility can be found in A SEAFOOD GREENHOUSE, SEA GRANT COLLEGE PROGRAM, UNIVERSITY OF DELAWARE (1977).

Drug, and Cosmetic Act² (FDCA) to the closed cycle mariculture of oysters. Mariculture presents an interesting laboratory to explore not only the structure of American food and drug law, but also the law's ability to respond to new developments in food technology. Of particular interest and importance is the question of whether the food and drug statute and its attendant regulations promote or inhibit the development of new technology in the food industry. While the overwhelming majority of technological developments is evolutionary, mariculture presents the opportunity to examine the applicability of the law to a totally new technology. As filter feeders, oysters are particularly sensitive to water pollution or contamination and may pass on to the consumer a variety of disturbing health consequences. Mariculture seeks to remedy this and other problems facing the oyster industry by recreating the ocean environment in a controlled setting. Thus, the purposes of mariculture and the purposes of the food and drug laws are the same: the protection of the public's health. If the food and drug laws preclude or substantially impede the development of mariculture as an industry, serious questions arise as to the law's efficacy.

Although the technology of mariculture is highly complex and subject to rapid evolution, an outline of processes involved and the ingredients utilized is necessary because food and drug problems cannot be addressed in the abstract; one must set forth the chemical, physical, and biological parameters of the food process in question. In its simplest terms mariculture involves the growing of algal foods in sea water, the addition of the algal food and sea water combination to oysters living in the mariculture facility, the removal of ammonia wastes from the oysters' habitat and its recycling into the algae production facility, and a perpetual repeat of the process punctuated by periodic harvest of the animals. Nitrates, phosphates, trace metals, and vitamins are added to sea water to form the phytoplankton nutrient media, and the addition of these components raises the most serious questions under the food additive provisions of the Food, Drug, and Cosmetic Act.³

2. Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1042 (1938) (current version codified at 21 U.S.C. §§ 301-392 (1976)) [hereinafter cited as FDCA § —, 21 U.S.C. § — (1976)]. The FDCA has been amended numerous times since 1938.

3. Refer to Appendix. Scientists hope that seawater may eventually be replaced by a combination of fresh water and synthetic sea salts.

II. LEGAL FRAMEWORK—ADDITIVES

Since the enactment of the first comprehensive federal food legislation in 1906,⁴ Congress has experimented with several regulatory mechanisms to protect the public from exposure to potentially harmful food products. The numerous amendments and re-enactments through which the legislation has passed over the years in an attempt to keep pace with the rapid technological progress of the food industry, together with the breadth and imprecision of the statutory language that has often been inconsistently interpreted and enforced by the courts and the responsible administrative agency, are the principal factors which have combined to make the area of federal food law unusually esoteric and complicated. The basic prohibition common to all versions of the legislation has been against the introduction of adulterated foods into interstate commerce. However, as is true of almost every significant term in the present and previous statutes, adulteration has both a common sense and a legal definition. Thus, according to section 402(a) of the FDCA, a food is adulterated as a matter of law (among other ways) if it contains a poisonous or deleterious substance which may render the food injurious to health, if it has as a component a regulated ingredient for which a tolerance has not been set, if it lacks a substance considered essential, or if it has been manufactured, produced, or kept under insanitary conditions.⁵ Because the original legislation⁶ was aimed at a specific evil and the subsequent revi-

4. Federal Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906) (repealed 1938) [hereinafter cited as Act of 1906, § ___, 34 Stat. ___ (repealed 1938)].

5. FDCA § 402, 21 U.S.C. § 342 (1976).

6. Section 7 of the 1906 Act provided that an article was adulterated:

In the case of confectionery:

If it contains terra alba, barytes talc, chrome yellow, or other mineral substance or poisonous color or flavor, or any other ingredient deleterious or detrimental to health, or any vinous, malt or spiritous liquor or compound or narcotic drug.

In the case of food:

First. If any substance has been mixed and packed with it so as to reduce or lower or injuriously affect its quality or strength.

Second. If any substance has been substituted wholly or in part for the article.

Third. If any valuable constituent of the article has been wholly or in part abstracted.

Fourth. If it be mixed, colored, powdered, coated, or strained in a manner whereby damage or inferiority is concealed.

Fifth. If it contain any added poisonous or other added deleterious ingredient which may render such article injurious to health: *Provided*, That when in the

sions were, for the most part, remedial,⁷ the difficulties associated with the area of federal food law are never more graphic than when attempting to apply the present statutory scheme to a new food process such as closed cycle mariculture. Such an application mandates and provides an opportunity for an examination of the history of federal food law and a functional analysis and integration of the various foods, food substances, and production and processing methods which are encompassed by the statutory and administrative regulation of the food industry.

III. SECTION 402 OF THE FDCA

A. History

The fundamental policy underlying federal food legislation is protection and enhancement of the public welfare through governmental supervision of the safety of foods and the marketing practices of the food industry.⁸ The constitutional foundation for federal laws embracing this policy is, of course, the Commerce Clause.⁹ The original approach toward regulation under the Federal Food and Drug Act of 1906 was the removal of food deemed adulterated or misbranded from interstate commerce,¹⁰ a concept which at the beginning of the century did not have the illimitable connotations of present day interpretation.¹¹ The 1906 Food and Drug Act provided for judicial seizure of adulterated foods found

preparation of food products for shipment they are preserved by any external application applied in such manner that the preservative is necessarily removed mechanically, or by maceration in water, or otherwise, and directions for removal of said preservative shall be printed on the covering or the package, the provisions of this Act shall be construed as applying only when said products are ready for consumption.

Sixth. If it consists in whole or in part of a filthy, decomposed, or putrid animal or vegetable substance, or any portion of an animal unfit for food, whether manufactured or not, or if it is the product of a diseased animal, or one that has died otherwise than by slaughter.

Act of 1906, § 7, 34 Stat. 769 (repealed 1938) (emphasis in original).

7. See *Developments in the Law—The Federal Food, Drug, and Cosmetic Act*, 67 HARV. L. REV. 632, 634 (1954).

8. *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399 (1914).

9. Congress is empowered to "regulate Commerce with foreign Nations, and among the several States . . ." U.S. CONST. art. I, § 8, cl. 3. See *Hypolite Egg Co. v. United States*, 220 U.S. 45 (1911); T. CHRISTOPHER, *CONSTITUTIONAL QUESTIONS IN FOOD AND DRUG LAWS* 2 (1960) [hereinafter cited as CHRISTOPHER].

10. Act of 1906, §§ 1-2, 34 Stat. 768 (repealed 1938).

11. See CHRISTOPHER, *supra* note 9, at 2-3.

in the interstate market¹² and made the shipment, delivery, or reception of adulterated or misbranded foods a federal offense regardless of the absence of criminal intent on the part of the violator.¹³ Because of the importance attributed to the congressional goal of preventing injury to the public, the law placed a strict burden of guaranteeing the wholesomeness of food on those who benefited financially from the sale or transportation of food items in interstate commerce.¹⁴

Adulteration under the 1906 Act had two major categories. One type of adulteration eventually came to be known as "economic adulteration" and was aimed at protecting the public from deceptive or dishonest practices of food manufacturers, including misbranding, substitution, or extraction of valuable constituents from foods, and concealment of inferior or damaged foods.¹⁵ The second major category of adulteration in the 1906 Act defined adulterated foods in the more usual sense of the phrase. Thus, a food was adulterated if it contained any "added poisonous or other added deleterious ingredient which may render such article injurious to health,"¹⁶ or if it consisted "in whole or in part of filthy, decomposed, or putrid animal or vegetable substance, or any portion of an animal unfit for food, whether manufactured or not, or if it is the product of a diseased animal, or one that has died otherwise than by slaughter."¹⁷ However, such terms as "adulteration," "added," "poisonous," or "deleterious ingredient which may render the article injurious to health," and "filthy, decomposed, or putrid," were not defined in any greater detail by the statute, but were left for future embellishment by the courts and the enforcement agency.¹⁸

It is noteworthy that, as a general rule, the attitude of the

12. Act of 1906, § 10, 34 Stat. 771 (repealed 1938).

13. *Id.* §§ 1-2, 34 Stat. 768.

14. See CHRISTOPHER, *supra* note 9, at 15-18.

15. Act of 1906, §§ 7-8, 34 Stat. 769 (repealed 1938).

16. *Id.* § 7, 34 Stat. 769.

17. *Id.*, 34 Stat. 769.

18. The Bureau of Chemistry in the Department of Agriculture was given authority to administer the domestic food provisions of the Act and to promulgate regulations in furtherance of Congressional intent. Act of 1906, §§ 3-5, 34 Stat. 768 (repealed 1938). In 1940, the responsibility for administration of federal food laws was transferred from the Department of Agriculture to the Food and Drug Administration (FDA) in the Federal Security Agency, which became the Department of Health, Education, and Welfare in April 1953. See Reorg. Plan. No. IV of 1940, § 12, 5 U.S.C. app., at 720 (1976); Reorg. Plan. No. 1 of 1953, § 8, 5 U.S.C. app., at 762 (1976).

courts toward federal food legislation has been one of singular deference to the responsible enforcement agency, and of liberal construction of the statutory language so as to effectuate to the greatest extent possible the legislative goals of protecting the consumer from dangerous products. As has often been stated by the judiciary, "regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely a selection of English words."¹⁹ It has been suggested that such an approach is more usual than not for health legislation, but in any event the Food and Drug Administration (FDA) and its predecessors have enjoyed "an almost unparalleled success in having its regulations and rules upheld."²⁰

Even in view of the generous discretion afforded to the enforcement agency by the courts by public policy considerations and by the imprecise statutory wording, administration of the food legislation has not been without its obstacles. A noticeable omission from coverage by the 1906 Act was that category of foods containing naturally occurring poisonous or deleterious substances. The word "added" in the phrase "added poisonous or other added deleterious substance" was defined by the Supreme Court in *United States v. Coca-Cola Co.*²¹ to mean a poisonous substance which had been artificially introduced into or on a food by man.²² The court referred to the legislative history of the 1906 legislation,²³ which manifested congressional intent to exclude from the status of adulteration those foods containing inherent poisons such as caffeine occurring naturally in food or oxalic acid in rhubarb, but not substances such as caffeine which had been added to a proprietary food like carbonated soft drinks. In two later circuit court cases²⁴ under the 1906 Act, both dealing with traces of arsenic found in a processed food, the courts held that when a substance which contained a naturally occurring poison was added to another substance, the compound was within the purview of the legislation as containing an added poisonous or deleterious substance even though the poison had not been directly added to the food by the

19. *United States v. Dotterweich*, 320 U.S. 277, 280 (1943).

20. CHRISTOPHER, *supra* note 9, at 3-4.

21. 241 U.S. 265 (1916).

22. *Id.* at 283.

23. *Id.* at 282-83. See H.R. REP. NO. 2118, 59th Cong., 1st Sess. 6-7, 11 (1906) [hereinafter cited as H.R. REP. NO. 2118]; 40 CONG. REC. 897 (1906).

24. *W.B. Wood Mfg. Co. v. United States*, 292 F. 133 (7th Cir. 1923); *Weeks v. United States*, 224 F. 69 (2d Cir. 1915).

manufacturer.²⁵

Although the 1906 Act did not consider foods containing natural poisons to be adulterated unless the substances were added by a producer or processor to another food, some foods were found to be adulterated under the "filthy, decomposed, or putrid" provisions even though the noxious components in the foods were not added within the standards set by *Coca-Cola*.²⁶ For the most part, the "filthy, decomposed, or putrid" language was construed to have an ordinary connotation. According to the courts,²⁷ the provision was intended to guarantee the cleanliness, the aesthetic quality, and the wholesomeness of foods reaching the consumer, while those foods composed of ingredients more immediately dangerous to the public were denounced under the "poisonous and deleterious" section.²⁸ But, in *United States v. Spague*,²⁹ unprocessed oysters contaminated with a bacterium absorbed from their natural environment were held to be adulterated because they consisted of "a filthy, decomposed, or putrid . . . substance." Although, as the court pointed out, the concept of "adulteration" would usually imply some human intervention, the term had a special meaning for purposes of the legislation and rendered a food made unwholesome by an act of nature one which was adulterated within the meaning of the statute, and consequently subject to the legislative sanctions.³⁰

The Department of Agriculture was seriously hampered in its enforcement of the 1906 Act by the necessity of having to establish the adulteration of food in judicial condemnation proceedings on a case-by-case basis.³¹ The Supreme Court in *United States v. Lex-*

25. *W.B. Wood Mfg. Co.*, 292 F. at 134; *Weeks*, 224 F. at 70.

26. Refer to notes 21-23 *supra* and accompanying text.

27. See, e.g., *United States v. 133 Cases of Tomato Paste*, 22 F. Supp. 515 (E.D. Pa. 1938).

28. Allegations of possible danger to the consumer fall within the "filthy, decomposed, and putrid" language of the FDCA. See *Salamonie Packing Co. v. United States*, 165 F.2d 205 (8th Cir.), *cert. denied*, 333 U.S. 863 (1948).

29. 208 F. 419 (E.D.N.Y. 1913).

30. *Id.* at 420, 422.

31. According to the FDA,

[a] complete elimination of all poisonous substances in foods is in some instances impossible. Where the presence of poisons is unavoidable their quantities must be kept so low that by no possibility will the food be harmful to the user. Where they may be dangerous in any quantity they should be absolutely prohibited. The present statute contains no provision authorizing either the complete prohibition of traces of poison in foods or the establishment of tolerances for poisons. On the contrary, it imposes upon the government the obligation of showing affirmatively

ington Mill & Elevator Co.³² compounded the difficulties of enforcement by requiring that the agency prove in each instance that a food containing an added poisonous or deleterious substance was dangerous to health because of the quantity of the poison found in the food rather than because of the mere presence of a substance considered poisonous.³³ Although the government's "per se" approach³⁴ was rejected by the court in this situation, the phrase "may be injurious to health" was given an expansive definition so that if the quantity or combined effect of an added poison in a food could possibly injure the health of any average consumer, the food would be considered adulterated as a matter of law.³⁵ The per se approach, however, was upheld in *United States v. R.C. Boeckel & Co.*,³⁶ a case which dealt with a substance added to a confectionary where the ingredient was one which had been specifically prohibited by the statutory language. In that situation, the court held the quantity of the substance in the food was not an issue.³⁷

In response to the problems created by the *Lexington Mill* interpretation with regard to added poisonous substances in foods other than confectionaries, the Department of Agriculture announced informal tolerances for some poisons such as arsenic and lead. The Department had no statutory authority to set tolerances under the 1906 Act, however, and thus the Department's informal tolerance levels had no legal status.³⁸

Although the 1906 Food and Drug Act had been amended on

in every instance that a food containing an added poisonous ingredient may be harmful to health under the conditions of use. The problem of establishing possible poisonous effects as a result of the consumption of minute quantities of poisonous ingredients in foods presents extreme difficulties. Without such proof a food containing an added poison cannot be condemned as adulterated. The government is not permitted in establishing its case under the terms of the present statute to take into consideration similar poisons in other items of the diet, although these may contribute to the total intake of the poison and be an important factor in determining the relative harmfulness of the adulterant.

FDA ANN. REP. 15 (1933).

32. 232 U.S. 399 (1914).

33. *Id.* at 411.

34. Under the per se standard, the presence of even a minute amount of a prohibited substance in a food product was in itself (per se) a violation of the 1906 Act. *Id.* at 407.

35. *Id.* at 412.

36. 221 F. 885 (1st Cir. 1915).

37. *Id.* at 889.

38. See Bellis, *Rulemaking Under § 406(a)*, 4 FOOD DRUG & COSM. L.Q. 488, 490 (1949).

several occasions,³⁹ Congress enacted the Food, Drug, and Cosmetic Act in 1938 after five years of hearings and revisions in an attempt to overcome the inadequacies and gaps encountered with the original legislation.⁴⁰ With regard to the adulteration of food⁴¹ because it contained or possibly contained a dangerous or unwholesome ingredient, the FDCA provided that:

A food shall be deemed to be adulterated (1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of the substance in such food does not ordinarily render it injurious to health; or (2) if it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of section 406;⁴² or (3) if it consists in

39. See Act of June 22, 1934, Pub. L. No. 73-451, ch. 712, 48 Stat. 1204 (adding § 10A to Act of 1906) (encompassing seafood inspection); Act of July 8, 1930, Pub. L. No. 71-538, ch. 874, 46 Stat. 1019 (amending Act of 1906, § 8) (allowing Secretary of Agriculture to promulgate standards of quality for canned foods); Act of Jan. 18, 1927, Pub. L. No. 69-552, ch. 39, 44 Stat. 1003 (amending Act of 1906, § 4) (reassigning certain responsibilities from the Bureau of Chemistry to the Food, Drug, and Insecticide Administration of the Department of Agriculture); Act of Mar. 4, 1923, Pub. L. No. 67-519, ch. 268, 42 Stat. 1500 (adding a section on the adulteration of butter); Act of July 24, 1913, Pub. L. No. 66-22, ch. 26, 41 Stat. 271 (amending Act of 1906, § 8) (extending the application of the word "packing" to include wrapped meals); Act of Mar. 3, 1913, Pub. L. No. 62-419, ch. 117, 37 Stat. 732 (amending Act of 1906, § 8) (provisions on packaging); Act of Aug. 23, 1912, Pub. L. No. 62-301, ch. 352, 37 Stat. 416 (amending Act of 1906, § 8) (misbranding of drugs).

40. S. REP. No. 493, 73d Cong., 2d Sess. 1 (1934) [hereinafter cited as S. REP. No. 493]. See also Kleinfeld, *Legislative History of the Federal Food, Drug, and Cosmetic Act*, 1 FOOD DRUG COSM. L.Q. 532 (1948).

41. FDCA § 201 defines food as "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." FDCA § 201(f), 21 U.S.C. § 321(f) (1976). If a manufacturer knows that an article not ordinarily used for food will be so used, then the article is subject to the statutory requirements. *Weeks v. United States*, 224 F. 69 (2d Cir. 1915). An article ordinarily used for food but intended for other purposes is also subject to the statute. *United States v. 13 Crates of Frozen Eggs*, 208 F. 950 (S.D.N.Y. 1913), *aff'd*, 215 F. 584 (2d Cir. 1914). Likewise, the term "component" has been construed to encompass even those ingredients which are never consumed without further processing. *United States v. O.F. Bayer & Co.*, 188 F.2d 555, 557 (2d Cir. 1951).

42. FDCA § 406, as codified, provides in pertinent part:

Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) of section 342(a); but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2) of section 342(a).

whole or in part of any filthy, putrid, or decomposed substance or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may become contaminated with filth or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.⁴³

The 1938 Act, therefore, expanded considerably the categories of food which were considered adulterated as a matter of law. The legislative history of the 1938 statute makes it clear that all food containing *any* poisonous or deleterious component might be subject to the legislative language of subsections 402(a)(1) and (2),⁴⁴ but the substantive standards were stated differently for added and nonadded ingredients. Foods containing nonadded poisonous ingredients were not adulterated if the quantity of the substance in the food would not ordinarily render the food injurious to health, while foods containing any other poisonous or deleterious substance would be adulterated if the substance might render the food injurious to health. With regard to added substances, however, the

While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 342(a). In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

FDCA § 406, 21 U.S.C. § 346 (1976).

43. *Id.* § 402, 21 U.S.C. § 342.

44. See S. REP. No. 493, *supra* note 40, at 3-4, which provides:

[The section on poisonous substances] applies to foods which by reason of the poisonous or deleterious constituent may be dangerous, irrespective of whether that constituent is added by man or put there by nature. Note that the phrase "may render" here used is the same as in the provision of the present law dealing with added poisons which "may render" the article injurious to health. This phrase is required, as a Federal judge once remarked, if the door is to be locked before the horse is stolen.

It is immaterial to the welfare of the consumer whether a poison in his food is introduced by artifice or occurs naturally. Such articles as Burma beans, naturally containing bydrocyanic acid, cannot be reached under the present act but would be subject to control under this provision. It would also apply to foods containing added poisons for which no tolerance had been set and which for that reason would not be subject to section 3(a)(2).

quantity of the poisonous ingredient no longer appeared to be of significance under the language of subsection 402(a)(2) and section 406, as any amount of a nonrequired or unavoidable poison for which a tolerance had not been set by the administrative agency was deemed unsafe.

The purpose of the provisions on added substances in the 1938 Act was, of course, to eliminate the necessity of the government having to prove affirmatively in every instance the potential health hazards of a substance added to a food by a producer or processor, and allowed the government to take into account the cumulative effect of poisons when setting tolerances.⁴⁵ In theory, at least, the government's burden in a food condemnation proceeding was lessened under the 1938 Act, as it was only necessary to show that a poisonous substance was an added one causing the food to be adulterated unless a tolerance for the poison had been established.⁴⁶ As a practical matter, however, the administrative experiences with the 1938 legislation were not significantly more satisfactory than with the earlier statute.

By the 1950's, a marked change in the habits of both the consumer and the food and related industries had been noted.⁴⁷ The

45. The Senate Report also provides:

In promulgating such regulations this section requires that there be taken into account the extent to which the use of the poison is required in the production of the article, as for example, poisonous sprays in producing certain fruits and vegetables, and likewise, the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances. This authorization will permit the establishment of comparatively liberal tolerances for any food where poison is unavoidable or is required by the necessities of production, and less liberal tolerances or complete prohibitions where it is practicable to limit the amount or poison in a particular food to every [sic] small quantities, or to eliminate it completely. It will likewise afford adequate control of those situations where irresponsible manufacturers, for some fancied or real commercial advantage, add dangerously toxic substances to foods, as, for example, the addition of maleic acid to fats and oils to prevent rancidity when preservation can be accomplished by observance of sanitary conditions in manufacture and packaging and by use of refrigeration for the finished product.

In approaching the problem of control from this angle the amount of added poisons can be so allocated to different foods, in accordance with the practical necessities, that on the basis of the probable consumption of the various foods consumers will not receive an aggregate quantity of poisons sufficient to jeopardize health. . . .

S. REP. NO. 493, *supra* note 40, at 3-4.

46. Markel, *The Food Additive Amendment of 1958*, 14 BUS. LAW. 514, 514 (1959) [hereinafter cited as Markel].

47. Larrick, *Social Implications of Modern Food Technology*, 14 FOOD DRUG COSM. L.J. 751, 751-53 (1959).

trend away from home-grown and prepared foods to public acceptance of packaged and shipped products together with a 25 percent increase in the population since 1938 placed a significantly more onerous burden on the FDA to ensure the quality and wholesomeness of foods and to protect the unwary consumer from potentially harmful food items. On the industry side, inflated demand and the effects of World War II spurred a plethora of technological innovations both in the production of raw agricultural commodities and the manufacture of processed foods.⁴⁸ Pesticides containing new ingredients which had been developed during and for use in the war had not been adequately tested for their long-term effects when residues of the chemicals were found remaining on foods for human and animal consumption. Because the majority of these chemicals were poisonous and also required in the production of agricultural products, the tolerance-setting provisions of section 406 could be triggered, but the establishment of such tolerances necessitated lengthy and cumbersome formal public hearing procedures which were not often employed.⁴⁹

Similar conditions existed with respect to other chemicals added directly or indirectly to food during commercial processing and the use of drugs and other substances administered to food-producing animals to cure or prevent disease and to artificially stimulate growth had become widespread.⁵⁰ Under the existing legislation, the FDA was required to prove that an ingredient found in a food was poisonous,⁵¹ and therefore the agency had to test each substance before it could take any action. Thus, the FDA was unable to prevent the use of an ingredient in a food simply because its safety was questionable or had not been demonstrated, thus fostering unfair competition among those food manufacturers who chose to undertake precautions in the use of untested food ingredients and those who chose to market their products without such safety measures.⁵²

48. *Id.* at 751-52.

49. See S. REP. NO. 1635, 83d Cong., 2d Sess. (1958), reprinted in [1954] U.S. CODE CONG. & AD. NEWS 2626, 2627 [hereinafter cited as S. REP. NO. 1635] (discussing the pesticide chemical amendment to the FDCA).

50. Refer to note 47 *supra*.

51. S. REP. NO. 2422, 85th Cong., 2d Sess. 1-2 (1958), reprinted in [1958] U.S. CODE CONG. & ADM. NEWS 5300, 5300 [hereinafter cited as S. REP. NO. 2422] (on the food additive amendments to the FDCA).

52. S. REP. NO. 2422, *supra* note 51, at 2, [1958] U.S. CODE CONG. & AD. NEWS at 5300-5301.

In addition, industry scientists contended that the use of the language in the 1938 Act deeming a food to be adulterated if it contained "any poisonous or deleterious substance which may render it injurious to health" demonstrated legislative approval of the *Lexington Mill* interpretation of similar wording in the 1906 Act as to the relativity of the phrase "poisonous or deleterious"; that is, the safety of a food ingredient, according to the industry, was to be judged by its use and effect in a food and not by the mere fact that the substance, standing alone, could be classified as poisonous, which was the construction urged by the government.⁵³ The food industry also felt that if a per se approach to poisonous substances were adopted, no legislative recognition could be given to those substances deliberately added to foods for beneficial purposes, as few of these food ingredients could meet the strenuous tolerance setting standards under section 406 of "unavoidable" or "required in the production of food."⁵⁴

Judicial and administrative records during the period between 1938 and the early 1950's indicate relatively little official activity in the area of poisonous ingredients in foods, especially in comparison to the time devoted by the courts and the agency to foods considered adulterated because of "filthy, decomposed, or putrid substances."⁵⁵ Notwithstanding, the FDA continued with its practice of announcing informal tolerances and policies on added substances in food, the theory being that since, in accordance with the agency's reading of the statute, any quantity of an added poison would cause a food to be adulterated, the agency could informally decide at what point it would take judicial action to have a food condemned.⁵⁶

53. See Markel, *supra* note 46, at 516; *Flemming v. Florida Citrus Exch.*, 358 U.S. 153 (1958).

54. 358 U.S. at 164-65. See S. REP. NO. 2422, *supra* note 51, at 2-3, [1958] U.S. CODE CONG. & AD. NEWS at 5301. See also C. DUNN, LEGISLATIVE RECORD OF THE 1958 FOOD ADDITIVE AMENDMENTS TO THE FDCA (1958).

55. See annotations collected at [1980] FOOD DRUG COS. L. REP. (CCH) ¶¶ 50,051, 50,057. See FDA ANN. REFS. (1940-1957), reprinted in 1-4 KLEINFELD & DUNN, *supra* note 47.

56. FDCA § 306, as currently codified, states that "[n]othing in this Act shall be construed as requiring the Secretary to report for prosecution or for the institution of libel or injunction proceedings, minor violations of this Act whenever he believes that the public interest will be adequately served by a suitable written notice or warning." FDCA § 306, 21 U.S.C. § 336 (1976). FDA informal tolerance levels and annotations of trade correspondences are collected in scattered sections of [1980] FOOD DRUG COS. L. REP. (CCH). See also *United States v. 449 Cases Containing Tomato Paste*, 212 F.2d 567, 575-81 (2d Cir. 1954).

The diverse needs of the public, the food industry, and the government resulted in amendments to section 402(a) on three separate occasions between 1954 and 1968,⁵⁷ representing a major shift from the previous corrective approach toward more preventive types of controls. This section presently states that a food will be deemed adulterated:

(a)(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) (A) if it bears or contains any added poisonous or added deleterious substance . . . which is unsafe within the meaning of section 406 of this title, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408(a)⁵⁸ of this title, or (C) if it is, or it bears or contains any food additive which is unsafe within the meaning of section 409 of this title⁵⁹ . . . , or

(Frank, J., dissenting), for a discussion of the FDA's extralegal system of tolerances.

57. See New Animal Drugs Act, Pub. L. No. 90-398, §§ 101-108, 82 Stat. 342 (1968) (codified at 21 U.S.C. § 306b (1976)); Food Additive Amendments of 1958, Pub. L. No. 85-929, 72 Stat. 1784 (1958) (current version at 21 U.S.C. §§ 201(s)-(t), 342(a)(2), 342(a)(7), 348 (1976)); Pesticide Chemicals in or on Raw Agricultural Commodities Act, Pub. L. No. 83-518, ch. 559, 68 Stat. 511 (1954) (current version at 21 U.S.C. § 346a (1976)). See also Color Additive Amendments, Pub. L. No. 86-618, §§ 101-105, 74 Stat. 397 (1960).

58. Section 408 of the FDCA, as currently codified, provides:

Any poisonous or deleterious pesticide chemical, or any pesticide chemical which is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of pesticide chemicals, as safe for use, added to a raw agricultural commodity, shall be deemed unsafe for the purposes of the application of clause (2) of section 342(a) of this title unless—

(1) a tolerance for such pesticide chemical in or on the raw agricultural commodity has been prescribed by the Administrator of the Environmental Protection Agency under this section and the quantity of such pesticide chemical in or on the raw agricultural commodity is within the limits of the tolerance so prescribed; or

(2) with respect to use in or on such raw agricultural commodity, the pesticide chemical has been exempted from the requirement of a tolerance by the Administrator under this section.

While a tolerance or exemption from tolerance is in effect for a pesticide chemical with respect to any raw agricultural commodity, such raw agricultural commodity shall not, by reason of bearing or containing any added amount of such pesticide chemical, be considered to be adulterated within the meaning of clause (1) of section 342(a) of this title.

FDCA § 408(a), 21 U.S.C. § 346a(a) (1976).

59. Section 409 of the FDCA, as currently codified, provides:

(a) A food additive shall, with respect to any particular use or intended use of

(D) if it is, or it bears or contains a new animal drug . . . which is unsafe within the meaning of section 512 of this title;⁶⁰ (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which

such additives, be deemed to be unsafe for the purposes of the application of clause (2)(C) of section 342(a) of this title, unless—

(1) it and its use or intended use conform to the terms of an exemption which is in effect pursuant to subsection (i) of this section; or

(2) there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used.

While such a regulation relating to a food additive is in effect, a food shall not, by reason of bearing or containing such an additive in accordance with the regulation, be considered adulterated within the meaning of clause (1) of section 342(a) of this title.

Id. § 409, 21 U.S.C. § 348.

60. FDCA § 512, dealing with new animal drugs, provides in pertinent part:

(a)(1) A new animal drug shall, with respect to any particular use or intended use of such drug, be deemed unsafe for the purposes of section 351(a)(5) and section 402(a)(2)(D) of this title unless—

(A) there is in effect an approval of an application filed pursuant to subsection (b) of this section with respect to such use or intended use of such drug,

(B) such drug, its labeling, and such use conform to such approved application, and

(C) in the case of a new animal drug subject to subsection (n) of this section and not exempted therefrom by regulations it is from a batch with respect to which a certificate or release issued pursuant to subsection (n) is in effect with respect to such drug.

(2) An animal feed bearing or containing a new animal drug shall, with respect to any particular use of intended use of such animal feed, be deemed unsafe for the purpose of section 351(a)(6) of this title unless—

(A) there is in effect an approval of an application filed pursuant to subsection (b) of this section with respect to such drug, as used in such animal feed,

(B) there is in effect an approval of an application pursuant to subsection (m)(1) of this section with respect to such animal feed, and

(C) such animal feed, its labeling, and such use conform to the conditions and indications of use published pursuant to subsection (i) of this section and to the application with respect thereto approved under subsection (m) of this section.

(3) A new animal drug or an animal feed bearing or containing a new animal drug shall not be deemed unsafe for the purposes of section 351(a)(5) or (6) of this title if such article is for investigational use and conforms to the terms of an exemption in effect with respect thereto under subsection (j) of this section.

Id. § 512, 21 U.S.C. § 360b.

has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (7) if it has been intentionally subject[ed] to radiation⁶¹

In essence, then, the mere presence or use of one of the enumerated ingredients in a food will cause a food containing it to be adulterated unless the substance is either generally recognized among experts and through supporting evidence to be safe for its intended purposes⁶² or it has received pre-market administrative approval and the approved substance found in the food does not exceed an established tolerance.⁶³ This regulatory approach, which was modeled after the new drug provisions in the original 1938 Act,⁶⁴ shifts the burden of testing and proving the safety of food ingredients from the government to the proponents of those substances,⁶⁵ thus remedying the defects in the statute created by the necessity of proving that an ingredient in a food is poisonous or harmful. However, because the present legislative wording contains numerous cross-references and deletions from coverage, and because the classes of substances adulterating a food under section 402(a) are not logically distinct, the most problematic aspect of the present statute is circumscribing the various categories under which particular food ingredients are to be regulated.

B. Added and Nonadded Poisonous Substances

As was previously noted, the 1906 Food and Drug Act did not consider a food to be adulterated because it contained inherent poisons.⁶⁶ In 1938, the language was revised so that foods containing any poisonous ingredient would be considered to be adulterated, but a different standard was applied to foods composed of nonadded poisons although the major emphasis of this legislation remained on controlling substances added to foods.⁶⁷ It would

61. *Id.* § 402, 21 U.S.C. § 342.

62. Refer to text accompanying notes 140-162 *infra* for a discussion of general recognition of safety.

63. Refer to text accompanying note 133 *infra*.

64. Act of 1938, §§ 201(g), 501, 52 Stat. 1040 (current version at 21 U.S.C. §§ 321(g), 351 (1976)).

65. See T. CHRISTOPHER & W. GOODRICH, CASES AND MATERIALS ON FOOD AND DRUG LAW 530-31 (2d ed. 1973).

66. Refer to notes 19-21 *supra* and accompanying text.

67. See FDCA § 402, 21 U.S.C. § 342 (1976).

seem that a common sense reading of the current statutory wording of subsections 402(a)(1) and (2)⁶⁸ would result in there being only two classes of poisonous substances—added or nonadded—which might cause food to be adulterated. If the poisonous substance is nonadded it will adulterate a food only if it is present in a quantity exceeding that ordinarily considered safe. With regard to added poisonous substances, however, depending upon whether the *per se* approach⁶⁹ is adopted, the quantity of the poison in the food may be of no significance but, at any rate, will cause a food to be adulterated if the substance is present in an amount which “may render [the food] injurious to health.” Alternatively, if any quantity of an added poisonous substance in a food considered unsafe under the terms of section 406 is sufficient to cause adulteration, then the “may render it injurious to health” language appears superfluous. The line between added and nonadded poisonous substances, therefore, has not been a clear one, for the FDA has urged a very liberal interpretation of “added” in order that a stricter regulatory standard would be applied.

In *United States v. An Article of Food*,⁷⁰ for example, the government contended that swordfish found to contain mercury in excess of the administrative guideline of 9.5 parts per million should be considered as containing an “added substance,” thus allowing the government to take advantage of either the “may render it injurious to health” language or the prohibition against avoidable or nonrequired added poisons or those unavoidable added poisons for which tolerances had not been set.⁷¹ The government argued that the test for determining whether a substance is added is whether it occurs naturally in the food. For instance, the government suggested that oxalic acid in rhubarb would not be considered an added substance. Likewise, the government reasoned that mercury is

68. FDCA § 402 provides, in pertinent part, that a food is adulterated:

(a)(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2)(A) if it bears or contains any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; (iii) a color additive; or (iv) a new animal drug) which is unsafe within the meaning of section 346 of this title. . . .

Id. § 402(a), 21 U.S.C. § 342(a).

69. Refer to notes 27 and 53 *supra*.

70. 395 F. Supp. 1184 (S.D.N.Y. 1975).

71. *Id.* at 1185.

not naturally produced by the fish; it is acquired through its external food supply.⁷² The court found this reasoning persuasive and rejected the food processors' argument that mercury could not be an added substance because it had been found in fish for centuries. Even assuming this to be the case, the court concluded that it added nothing to the question of whether mercury is naturally produced by fish and thus whether it is an added substance within the meaning of the statute.⁷³

This approach was criticized in the literature⁷⁴ and a different approach was taken in the case of *United States v. Anderson Seafoods, Inc.*⁷⁵ This case also involved swordfish containing mercury which the United States claimed were adulterated because mercury is an "added substance" in swordfish which "may render" the fish injurious.⁷⁶ The FDA did not seriously contend that the swordfish in question were "ordinarily injurious to health," although the defendant argued that mercury was not a substance that was added to swordfish and that the fish must be judged by the "ordinarily rendered injurious" standard.⁷⁷ The FDA urged that an added substance was one that is not inherent or essential to the organism from which the food is derived. Under this reasoning, nature's own contaminants would be added under the Act's meaning. The FDA relied on language in both court decisions and portions of the legislative history, but placed its primary emphasis on a regulation that defined an added substance as one which is not "an inherent natural constituent of the food," but rather is the "result of environmental, agricultural, industrial, or other contamination."⁷⁸

The FDA did not argue for the application of the rather extreme position of *United States v. An Article of Food*, which stands for the proposition that any material obtained from the environment is an added substance, and the court found that ruling to be contrary to the legislative history of the Act and thus not persuasive authority. The court noted that even the greatest deference to the FDA's rule would not require or permit a court to accept an interpretation contrary to the legislative history and to the

72. *Id.* at 1186.

73. *Id.*

74. See generally Note, *Health Regulation of Naturally Hazardous Food: The FDA Ban on Swordfish*, 85 HARV. L. REV. 1025 (1972).

75. 447 F. Supp. 1151 (N.D. Fla. 1978).

76. *Id.* at 1153.

77. *Id.* at 1154.

78. 21 C.F.R. § 109.3(c) (1980).

Supreme Court. The court in *Anderson Seafoods* further observed that the history of the Food, Drug, and Cosmetic Act identified the distinction between added and nonadded substances as that between human acts and acts of nature,⁷⁹ and noted that the Supreme Court in *United States v. Coca-Cola Co.*⁸⁰ had made the same distinction in construing the "added ingredient" provisions of the 1906 Act.⁸¹

The evidence introduced in *Anderson Seafoods* showed that the food supply is the primary source of mercury in swordfish, and that in the estuaries and shelf areas human activities contribute about two-thirds of the mercury found in the upper 6 to 8 inches of sediment, which serves as the beginning of the swordfish's food chain. The court, thus, found it clear that some portion of the mercury finding its way into swordfish comes from human contribution to the food chain, and held that that portion was an added substance under the FDCA.⁸²

The regulation construed in *Anderson Seafoods* is still in effect and defines a "naturally occurring poisonous or deleterious substance" as a poisonous or deleterious substance that is an inherent natural constituent of a food and is not the result of environmental, agricultural, industrial, or other contamination.⁸³ An added poisonous or deleterious substance, according to the regulation, is one that is not a naturally occurring poisonous or deleterious substance.⁸⁴ Thus the rule, in effect, defines an added substance as one which is not an inherent natural constituent of the food but rather is the result of environmental, agricultural, industrial, or other contamination. To this, *Anderson Seafoods* adds the requirement that the substance be artificially introduced or attributable to human acts or intervention.

An illustration utilizing the toxin produced by the paralytic shellfish virus demonstrates the effect of the *Anderson Seafoods* approach. The paralytic shellfish virus produces a toxin that is a poisonous substance but is not an inherent natural constituent of

79. See H.R. REP. NO. 2118, *supra* note 23, at 6-7, 11 (1906); S. REP. NO. 493, *supra* note 40, at 3 (1934); 40 CONG. REC. 1133 (1906).

80. 241 U.S. 265 (1916). Refer to notes 21-25 *supra* and accompanying text.

81. 447 F. Supp. at 1155.

82. *Id.* For a detailed description of the scope of human contribution to mercury in seafood, see Note, *Health Regulation of Naturally Hazardous Foods: The FDA Ban on Swordfish*, 85 HARV. L. REV. 1025 (1972).

83. 21 C.F.R. § 109.3(c) (1980).

84. *Id.* § 109.3(d).

oysters; neither is it the result of environmental, agricultural, industrial, or other contamination.⁸⁵ Thus, under the definition of naturally occurring poisonous or deleterious substance in the federal regulations, paralytic shellfish toxin would be regulated as an added substance. It would seem to stretch credulity to urge that this virus, which is certainly naturally occurring within the common usage of the word, should not be considered naturally occurring under the law. However, *Anderson Seafoods* can be read to modify not the definition of naturally occurring but rather the definition of an added substance. The court said, "The term 'added' as used in section [402(a)(1)] means artificially introduced, or attributable to the acts or intervention of man."⁸⁶ Considered in light of the regulation's definition of an added poisonous or deleterious substance, that definition becomes "a poisonous or deleterious substance that is not a naturally occurring poisonous or deleterious substance and is artificially introduced, or attributable to the acts or intervention of man." This construction would leave a gap in the regulatory scheme as the paralytic shellfish toxin would not fall into either category. The paralytic shellfish toxin would not be a naturally occurring poisonous substance because it is not an inherent natural constituent of the food, and would not be an added substance because it has not been artificially introduced or attributable to human acts or intervention. The FDA apparently interprets *Anderson Seafoods* to alter the definition of "naturally occurring," because it recognizes no gap in the regulatory scheme where paralytic shellfish toxin is involved. This is illustrated by the fact that an action level for paralytic shellfish toxin in clams, mussels, and oysters, the level that represents the limit at or above which the FDA will take legal action against a product to remove it from the market, has been established and is enforced.⁸⁷

The human intervention approach is particularly significant where, as in the case of closed cycle mariculture, scientists attempt to artificially recreate nature's products. The legislative history makes it clear that the less rigorous standard applied to naturally occurring substances would not be applicable where an additive is a substance which is naturally occurring in the food. For example,

85. See G. ROUNSEFELL, *ECOLOGY, UTILIZATION, AND MANAGEMENT OF MARINE FISHERIES* 64 (1978).

86. 447 F. Supp. at 1155.

87. The action levels for paralytic shellfish toxin in these seafoods is 80 micrograms per 100 micrograms of meat. [1980] 3 FOOD DRUG COS. L. REP. (CCH) ¶ 50,285.

if a coffee processor subjects coffee to a procedure in which the naturally occurring caffeine is removed and later replaced with an equal amount of identical caffeine, the caffeine is considered an added substance.⁸⁸ As noted in *Anderson Seafoods*, it appears from the legislative history that Congress felt that human activities were qualitatively different from the work of nature.⁸⁹

A somewhat different problem is presented when the substance being considered is, or is argued to be, an inherent component of the food product. In *United States v. 1232 Cases American Canned Beauty Brand Oysters*,⁹⁰ fragments of oyster shell found in canned oysters were held not to be "added" within the meaning of section 402. The court noted that in the canning process it is necessary to remove the rough, irregular shell so far as that may be accomplished and that the shell fragments, therefore, are not artificially added for the purpose of growth or to aid in the processing operation.⁹¹ It might well be argued, however, that while oyster shell is an inherent component of oysters, it is not an inherent component of oyster meat and that shell fragments have in fact been added to oyster meat by the processing procedure, because there were no oyster shell fragments in the meat while the oyster was alive. The FDA regulations say that a naturally occurring deleterious substance is an inherent natural constituent of a food, and it seems reasonable to argue that the food of an oyster is the meat and that shell fragments are not an inherent natural constituent of the meat. Contrarily, it might be argued that the evidence in *United States v. 1232 Cases American Canned Beauty Brand Oysters* showed that oyster shell is not a poisonous or deleterious substance.

An example of a substance that is almost certainly not an "added substance" under any interpretation is provided in the case of *Millet, Pit and Seed Co., Inc. v. United States*,⁹² where the court

88. *Hearings on H.R. 6906, H.R. 8805, H.R. 8941, and S. 5 Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce*, 74th Cong., 1st. Sess. 58 (1935).

89. 447 F. Supp. at 1156. As will be demonstrated, it also seems highly likely that the caffeine would be considered a food additive (or generally recognized as safe), and each component of the mariculture process, even if its aim is to recreate nature, must also be considered in that light.

90. 43 F. Supp. 749 (W.D. Mo. 1942).

91. The court also noted that the claimant had proved that over 50 million cans had been processed and distributed and that no complaints had ever been made about the presence of shell fragments. *Id.* at 750.

92. 436 F. Supp. 84 (E.D. Tenn. 1977).

found that the potentially poisonous substance amygdalin found in apricot kernels was not an added substance. Stating the test for determination of whether a substance is added to be whether it occurs naturally in the food,⁹³ the court noted that the substance occurs naturally in apricot kernels and therefore the government must prove that the kernels contained a quantity of the poisonous substance sufficient to render them injurious to health under ordinary conditions of usage. Noting further that amygdalin occurs naturally in over 1,200 fruits, vegetables, grains, and seeds, the court found that the ordinary use of the apricot kernel as a food would not be injurious to the health of the consumer.⁹⁴

One obvious deficiency in the FDA's reasoning regarding non-added and added poisons is that the agency has transformed the categories into inherent and noninherent poisons. Nowhere in the 1906 Food and Drug Act or in the present statute do the phrases "naturally occurring" and/or "inherent" poisonous substances appear, although some support can be found in the legislative history of the 1938 statute for construing a "nonadded" ingredient as one which inheres naturally in a food.⁹⁵ However, the interpretation of the term "added" as meaning any substance *not* occurring naturally in a food, as the *Anderson Seafoods* court suggested, cannot be substantiated. There is little doubt that the concern of Congress when it enacted the added poisons provisions in both the 1906 and 1938 versions of the food legislation was with those harmful or potentially dangerous ingredients incorporated into food by some human act which could best benefit from governmental controls.⁹⁶ In particular, the primary focus of the food legislation has, since its inception, been on supervision of the food manufacturing and processing industries.⁹⁷ Because safeguarding the consumer is the major goal of federal food law, however, Congress also probably desired to ensure that some mechanism existed for removing any harmful food product from the market whether or not the food had been contaminated by human intervention and whether or not the

93. See *United States v. An Article of Food*, 395 F. Supp. 1184 (S.D.N.Y. 1975). This case was strongly criticized in *Anderson Seafoods*.

94. 436 F. Supp. at 87-88. When used as a drug, amygdalin is known as laetrile, and federal courts have expended much energy in the determination of how this substance should be regulated as a drug.

95. See S. REP. NO. 493, *supra* note 40, at 3-4. Refer to note 45 *supra*.

96. *United States v. Ewig Bros. Co.*, 502 F.2d 715, 722 (7th Cir. 1974), *cert. denied*, 420 U.S. 945 (1975).

97. *Id.*

product had been intentionally or otherwise contaminated or held by the person against whom the legislative sanctions were being enforced. It seems reasonable, therefore, that a different but less burdensome standard would be established for those ingredients found in food as a result of some human intervention as opposed to those poisons from other sources which must be proven to be "ordinarily injurious to health." Thus, if the only characteristic which Congress intended to distinguish between added and nonadded poisons is human intervention, then mercury added to the food chain at some point and migrating through the ecosphere to contaminate swordfish may well be, as was held by the *Anderson Seafoods* court, an added poisonous or deleterious ingredient within the meaning of the FDCA. Therefore, the fish would be adulterated if the mercury were present in a quantity which could render the food injurious to health unless the mercury were unavoidable or required in the production of food, in which case a tolerance is required by section 406 before its presence can be sanctioned.

As was discussed, another difficulty with the present interpretations of the added/nonadded categories concerns the appropriate treatment for harmful substances like aflatoxin,⁹⁸ salmonella⁹⁹ or paralytic shellfish disease, which would not fall into either classification when "added" is defined as requiring some human act and "nonadded" means inherent in the food. Traditionally, these types of food components were likely to cause food to be adulterated under the "filthy, putrid, or decomposed substance" or "otherwise unfit for food" provisions of subsections 402(a)(3) and (4), but it would not be inconsistent to also classify them as poisonous substances¹⁰⁰ whose presence may render a food injurious to health under the language of subsection 402(a)(1).

The possibility thus exists that there are three categories of poisonous substances which will cause the adulteration of food

98. See *United States v. Boston Farm Center, Inc.*, 590 F.2d 149 (5th Cir. 1979).

99. See *United States v. 1200 Cans Pasteurized Whole Eggs*, 339 F. Supp. 131 (N.D. Ga. 1972); *United States v. Sars of La., Inc.*, 324 F. Supp. 307 (E.D. La. 1971).

100. Section 402 provides, in pertinent part:

A food shall be deemed adulterated . . .

(a) . . . (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health.

FDCA § 402, 21 U.S.C. § 342 (1976). Refer to text accompanying notes 39-46 *supra*.

under subsections 402(a)(1) and (2): those poisonous ingredients added to food by man that are unsafe under section 406 unless a tolerance for their use has been established; inherent poisons which exceed a level ordinarily considered safe; and all other poisons which may render a food injurious to health. Unfortunately, this interpretation, although analytically useful, does not eliminate the requirement that the FDA demonstrate in each instance the poisonous nature of a substance before any action can be taken to condemn a food bearing such a substance. In addition, there has yet to be a decisive judicial or legislative answer under the 1938 version of the legislation on the issue of whether the mere presence of an added or noninherent ingredient considered poisonous will automatically render a food containing it per se adulterated or whether the quantity of a poison in a food must be considered in determining adulteration under subsections 402(a)(1) and (2). The problems created by the uncertain interpretations and regulation of potentially harmful substances added to food led Congress to adopt a regulatory approach which forbids the addition of any substance to food unless proven or recognized as safe for their intended uses.

C. Separately Regulated Ingredients Under Section 402(a).

When Congress enacted the pesticide, food additive, and animal drug amendments to the FDCA, there was no longer a requirement that an ingredient falling within one of the enumerated categories be shown to be poisonous before its presence in a food would cause adulteration, and these identified food ingredients were excluded from the category of added poisons. Subsection 402(a)(2)(A) now basically provides that a food will be deemed adulterated if it contains any added poisonous substance.¹⁰¹

The food additive category is the most comprehensive class of regulated ingredients under the FDCA, and it is defined for purposes of the Act in section 201 as "any substance the intended use of which results or may reasonably be expected to result, directly

101. Section 402 provides that a food is adulterated if it bears or contains any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; (iii) a color additive; or (iv) a new animal drug) which is unsafe within the meaning of section 346 of this title. . . . FDCA § 402(a)(2)(A), 21 U.S.C. § 342(a)(2)(A) (1976). Pesticides on raw agricultural commodities, food additives, or new animal drugs are deemed unsafe in § 406.

or indirectly in its becoming a component or otherwise affecting the characteristic of any food . . . if such substance is not generally recognized . . . as having been adequately shown . . . to be safe."¹⁰² According to the legislative history, the definition of food additives was restricted to those substances intentionally or incidentally added to food, "*including* any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting or holding food."¹⁰³ Accidental additives that, if properly used, would not reasonably be expected to become a component of food, were not included within the definition of food additives and remain, where applicable, in the category of poisonous substances regulated under subsection 402(a)(1) or (2).¹⁰⁴ The examples of accidental additives cited by the Senate Report on the food additive amendments are such poisonous compounds as paints and cleaning solutions which are used in food processing plants but somehow get into processed foods.¹⁰⁵ The category of incidental additives would cover substances migrating to food from its packaging.¹⁰⁶ These examples do not, however, appear to be exhaustive of the types of substances included within the categories.

All nonaccidentally added poisons are, therefore, encompassed within the statutory definition of food additives, but the food additive category is the more expansive one because the character of a substance as poisonous is not relevant to the classification; the mere existence of an "unsafe" food additive in a food encompassed within the statutory definition will render the food adulterated as a matter of law.¹⁰⁷

Because of the sweeping language defining food additives in the FDCA, it would be possible to categorize residues of pesticides¹⁰⁸ and animal drugs¹⁰⁹ when found in or on a food as food

102. *Id.* § 201(s), 21 U.S.C. § 321(s).

103. C. DUNN, LEGISLATIVE RECORD OF 1958 FOOD ADDITIVE AMENDMENT TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT 11-12 (1958) (emphasis added) (citing H.R. REP. NO. 2284, 85th Cong., 2d Sess. (1958), reprinted in [1958] U.S. CODE CONG. & AD. NEWS 5300.)

104. *Id.* at 63 (citing S. REP. NO. 2422, *supra* note 51).

105. *Id.*

106. *Natick Paperboard v. Weinberger*, 525 F.2d 1103 (1st Cir. 1975); *United States v. Articles of Food Consisting of Pottery*, 370 F. Supp. 371 (E.D. Mich. 1974).

107. Department of HEW, Notice of Proposed Rulemaking on Poisonous or Deleterious Substances in Food, 39 Fed. Reg. 42,743, 42,744 (1974).

108. Subsection 402(a)(2)(B), as currently codified, provides that a food is adulterated "if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 346a(1) of this title. . . ." FDCA § 402(a)(2)(B), 21

additives were it not for the specific references in the legislation deleting these substances from coverage under the food additive

U.S.C. § 342(a)(2)(B) (1976). Section 201 of the FDCA defines the term "pesticide chemical" as "any substance which, alone, in a chemical combination or in formulation with one or more other substances is 'a pesticide' within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act . . . and which is used in the production, storage, or transportation of raw agricultural commodities." FDCA § 201(g), 21 U.S.C. § 321(g) (1976). A "raw agricultural commodity" is "any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing." FDCA § 201(r), 21 U.S.C. § 321(r) (1976). "Pesticide" is defined in the Federal Insecticide, Fungicide, and Rodenticide Act as "(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant." 7 U.S.C. § 136(u) (1976).

According to the current codification of § 408 of the FDCA, a pesticide chemical which is

generally recognized among experts qualified by scientific training and experience to evaluate the safety pesticide chemicals, as safe for use, added to raw agricultural commodity, shall be deemed unsafe for purposes of the application of clause (2) of 342(a) of this Title unless:

(1) a tolerance for such pesticide chemical in or on the raw agricultural commodity has been prescribed by the Administrator of the Environmental Protection Agency under this section and the quantity of such pesticide chemical in or on the raw agricultural commodity is within the limits of the tolerance so proscribed; or

(2) with respect to use in or on such raw agricultural commodity, the pesticide chemical has been exempted from the requirement of a tolerance by the Administrator under this section.

While a tolerance or exemption from tolerance is in effect for a pesticide chemical with respect to any raw agricultural commodity, such raw agricultural commodity shall not, by reason of bearing or containing any added amount of such pesticide chemical, be considered to be adulterated within the meaning of clause (1) of section 342(a) of the title.

FDCA § 408(a), 21 U.S.C. § 346a(a) (1976).

109. Under the provisions of the Food, Drug, and Cosmetic Act, new animal drugs and animal feeds containing new animal drugs are subject to regulation and pre-market approval by the FDA. See FDCA § 512, 21 U.S.C. § 360b (1976). Basically, the words "drug," "food," and "animal feed" are defined in the Act in terms in which these words are commonly understood. See FDCA § 201(f), (g), (x), 21 U.S.C. § 321(f), (g), (x) (1976). A new animal drug, however, has a specific definition for purposes of the Act. If a drug is intended to be given directly to an animal or to be mixed in an animal feed, it is a new animal drug, unless, (1) it is a drug whose use was previously regulated under the Food and Drug Act of 1906 prior to the enactment of the Food, Drug, and Cosmetic Act in 1938; or (2) it is a drug that is generally recognized as safe (GRAS) and effective for its intended purpose by qualified experts in the field of animal medication; or (3) it is a drug that, even though generally recognized as safe, has not been widely used. FDCA § 201(w), 21 U.S.C. § 321(w) (1976). A new animal drug is also any antibiotic drug intended for use with animals or in animal feed, whether or not generally recognized as safe or previously regulated under the earlier Act, if it is composed wholly or partly of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, and if the antibiotic drug has not been specifically exempted by FDA regulations. *Id.*, 21 U.S.C. § 321(w).

definition in section 201(s).¹¹⁰ Although no conceptual difficulties existed under the original language or interpretations of the FDCA in classifying pesticide chemicals which are unavoidable or required in the production of food as added poisons under section 402(a)(2), and thus making them subject to the FDA's tolerance setting authority under section 406, the separate regulation of pesticides simplified the procedural requirements associated with the establishment of such tolerances.¹¹¹ Similarly, drugs administered to animals or added to animal food also become a distinct category under the FDCA so that the law concerning these substances would be consolidated and the approval procedure expedited.¹¹² Prior to the 1968 amendment, animal drugs were regulated under the new drug and food additive or poisonous substances sections of the FDCA.¹¹³ With regard to pesticides on processed foods, subsection 402(a)(2)(C), in referring to the adulteration of food containing an unsafe food additive, provides that such a food will not be considered adulterated as containing an unsafe food additive as long as the residue of the chemical on the processed item does not exceed a tolerance established under the regulatory mechanism for pesticides on the raw commodity.¹¹⁴

Although the common types of food substances and industry

110. The FDCA defines a "food additive" as any substance the intended use of which results . . . in its becoming a component or otherwise affecting the characteristics of any food . . . except that such term does not include:

- (1) a pesticide chemical in or on a raw agricultural commodity; or
- (2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or
- (3) a color additive; or
- (4) any substance used in accordance with a sanction or approval granted prior to September 6, 1958, pursuant to this chapter, the Poultry Products Inspection Act . . . or the Meat Inspection Act . . .; or
- (5) a new animal drug.

FDCA § 201(s), 21 U.S.C. § 321(s) (1976).

111. See S. REP. NO. 1635, *supra* note 49, [1954] U.S. CODE CONG. & AD. NEWS at 2627 (concerning pesticide amendments to the FDCA).

112. See S. REP. NO. 1308, 90th Cong., 2d Sess. (1968), *reprinted in* [1968] U.S. CODE CONG. & ADM. NEWS 2607, 2608 (FDCA amendments dealing with animal drugs).

113. Section 512(k), as currently codified, states:

While approval of an application for a new animal drug is effective, a food shall not, by reason of bearing or containing such drug or any substance formed in or on the food because of its use in accordance with such application . . . be considered adulterated within the meaning of clause (1) of section 342(a) of this title.

FDCA § 512(k), 21 U.S.C. § 360b(k) (1976).

114. *Id.* § 408, 21 U.S.C. § 346a.

activity that were plainly intended to be regulated as food additives, pesticides on raw commodities, or new animal drugs are not difficult to discern from the statutory wording, those factual situations which are less obvious or which were not likely anticipated by Congress when the amendments were adopted have created more conceptual difficulties for the courts and the FDA. In *United States v. Vita Food Products of Illinois, Inc.*,¹¹⁵ for example, the government sought to have smoked chubs declared adulterated under the food additive provisions of the FDCA. The fish were found to contain residues of DDT and Dieldrin, pesticides absorbed by the fish from their natural environment and for which tolerances had not been established under the pertinent provisions of the FDCA, although "interim guidelines" for residues of the chemicals on fish had been announced by the FDA.¹¹⁶ In a related case,¹¹⁷ raw fish containing residues of pesticide were also seized as bearing unsafe pesticides on a raw agricultural commodity because no tolerances for the use of the chemicals had been approved.¹¹⁸

The Seventh Circuit, in reversing the lower court's refusal to classify the chemicals on the smoked chubs as food additives, focused on the character of the substance rather than the source, and held that prior to processing the chemicals were pesticides on a raw agricultural commodity where their presence would render the fish adulterated unless the proper procedural requirements had not

115. 356 F. Supp. 1213 (N.D. Ill. 1973), *rev'd sub nom.* *United States v. Ewig Bros. Co.*, 502 F.2d 715 (7th Cir. 1974), *cert. denied*, 420 U.S. 945 (1975).

116. 502 F.2d at 724-25.

117. On appeal, *Vita Food* was consolidated with *United States v. Ewig Bros. Co.* The FDA had sued Ewig Brothers and five other distributors of raw chubs in the federal district court in the Eastern District of Wisconsin, claiming adulteration of fish which contained unsafe pesticides on raw agricultural commodities. See *United States v. Goodman*, 353 F. Supp. 250 (E.D. Wis. 1972), *aff'd*, 486 F.2d 847 (7th Cir. 1973). The district court granted the FDA's requested injunction against all six defendants. The FDA sued *Vita Food Prods. of Ill., Inc.*, seeking to enjoin them from distributing the smoked chubs which allegedly contained unsafe food additives. The lower court held for *Vita*, finding that residues of the pesticides were not food additives within the meaning of the FDCA and, even if considered poisonous or deleterious substances, were not injurious to health. *United States v. Vita Food Prods. of Ill., Inc.*, 356 F. Supp. 1213, 1217-19 (N.D. Ill. 1973), *rev'd sub nom.* *United States v. Ewig Bros. Co.*, 502 F.2d 715 (7th Cir. 1974), *cert. denied*, 420 U.S. 945 (1975).

The appellate court in *Goodman* also affirmed the lower court's holding that the EPA would not be required to establish a tolerance regulation for DDT on fish before injunctive relief could be granted on the basis that the fish contained unsafe pesticide residues when the definition of "unsafe" under the terms of the FDCA meant that no tolerance had been established. 486 F.2d at 853-55.

118. 502 F.2d at 722-25.

met.¹¹⁹ Once processed, however, the chemicals became food additives within the meaning of the FDCA, thus causing the fish to be adulterated, since the presence of the chemicals on the smoked chubs did not conform to existing tolerances for residues of the pesticide on the raw item.¹²⁰

In supporting its decision to give the food additive category such an expansive application, the *Vita Food* court pointed to the underlying policies and history of federal food law culminating in the food additive amendments, and stated that no reason could be found in the language of the amendment or its history to limit the definition of food additives to those substances added to a food by a processor. The court felt that to hold otherwise would lead to the anomalous result of having the raw fish be considered per se adulterated under the pesticide chemical on raw commodities provisions while the processed fish were subjected to a case-by-case determination under the poisonous substances section.¹²¹ The Seventh Circuit also pointed to the provision in subsection 402(a)(2)(C), which excluded from the application of food additive adulteration those pesticide residues on processed foods conforming to approved tolerances for the raw items, as an indication of congressional intent that all pesticides on processed food not meeting these tolerances were to be treated as food additives even where the chemical could not be classified as an intentional or incidental additive.¹²²

In *Vita Food*, the FDA's claim that the smoked chubs were adulterated under the food additive provisions was apparently predicated on the government's desire to have the stricter food additive standards applied, thus avoiding the burden of proving that the chubs contained a poisonous or deleterious substance which might render the fish injurious to health or of arguing per se adulteration under the added poisons provision. In the sense that both cases concerned the environmental contamination of fish with dangerous chemicals added indirectly to the food chain by man, *Vita Foods* is factually analogous to *Anderson Seafoods*, but the FDA did not urge the *Anderson Seafoods* court to classify mercury in the swordfish as a food additive. In *Vita Food*, the court relied on the nature of the offending substances as pesticides to conclude

119. *Id.* at 722-23.

120. 502 F.2d at 723-24.

121. *Id.* at 721-22.

122. *Id.* at 722-23.

that once the fish were processed, the chemicals were automatically transformed into food additives.¹²³ Neither the *Vita Food* nor the *Anderson Seafoods* courts analyzed the problem as to whether the substances at issue were accidental, as opposed to incidental or intentional additives which, according to the legislative history, appears to be the feature that distinguishes added poisons from food additives.¹²⁴ It has been suggested, however, that the factual circumstances of environmental contamination, as presented to the *Vita Food* and the *Anderson Seafoods* courts, may not easily fit into either the accidental added poisons or the incidental food additive categories as those classifications were conceived by Congress. If reconciled, however, the *Vita Food* and *Anderson Seafoods* cases would allow almost every substance, poisonous or not, which becomes incorporated into food directly or indirectly through some human intervention, no matter how remote or unintentional, to be regulated as a food additive under the FDCA.¹²⁵

An interesting problem raised by this analysis and not discussed by the *Vita Food* court concerns the substantive standards required for determining the safety of a food additive under section 409 before its use in or presence on a food is permitted. The Delaney Clause of section 409 prohibits the FDA from establishing a tolerance for any food additive that has been found to induce cancer in humans or animals.¹²⁶ Since recent tests on DDT, for ex-

123. *Id.* at 722.

124. Refer to notes 79-80 *supra*.

125. See Note, 21 VILL. L. REV. 140, 148 (1975).

126. Section 409(c)(3), as currently codified, states:

(3) No such regulation shall issue if a fair evaluation of the data before the Secretary—

(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe: Provided, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal, except that this proviso shall not apply with respect to the use of a substance as an ingredient of feed for animals which are raised for food production, if the Secretary finds (i) that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (ii) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (f) and (g) of this section) in any edible portion of such animal after slaughter or in any food yielded by or derived from the living animal . . .

ample, have shown it to be a carcinogen, the effect of classifying the chemical as a food additive is to cause any food containing residues of DDT to be deemed adulterated as a matter of law. In addition, section 409 also prohibits the FDA from fixing a tolerance for a food additive at a level higher than that required to accomplish the physical or other technical effect for which the additive is intended.¹²⁷ Such substances as mercury or DDT, of course, serve no useful function when found on fish although their presence is likely unavoidable. The practical consequences of present legislative and judicial interpretation regarding these substances, therefore, may be to ban all seafood which is found containing man-made contaminants derived from the environment.¹²⁸

Most of the complexities associated with section 402 of the FDCA are the result of the failure on the part of Congress to have precisely delineated which substances or categories of substances it wished to have regulated under the various provisions. The legislative history makes it clear that in enacting the food additive amendments, Congress was primarily concerned with the regulation of those substances intentionally or incidentally added to the food by the food processing industry,¹²⁹ but the *Vita Food* court was also correct when it noted that there is no language in the statute or its history to indicate that such an application was intended to be exclusive and the pertinent wording can be read to reach such substances present in food from sources other than food processing or manufacturing. The pesticide amendments were, however, aimed at controlling a particular type of substance found

FDCA § 409(c)(3), 21 U.S.C. § 348(c)(3) (1976).

127. See FDCA § 409(c)(4), 21 U.S.C. § 348(c)(4) (1976), which states, in pertinent part:

(4) If, in the judgment of the Secretary, based on a fair evaluation of the data before him, a tolerance limitation is required in order to assure that the proposed use of an additive will be safe, the Secretary—

(A) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the physical or other technical effect for which such additive is intended; and

(B) shall not establish a regulation for such proposed use if he finds upon a fair evaluation of the data before him that such data do not establish that such use would accomplish the intended physical or other technical effect.

128. See Note, *Health Regulation of Naturally Hazardous Foods: The FDA Ban of Swordfish*, 85 HARV. L. REV. 1026 (1972). See also 21 C.F.R. § 193.120 (1980) (establishing tolerances of DDT in specific foods).

129. See S. REP. NO. 2422, *supra* note 51, at 4-5, [1958] U.S. CODE CONG. & AD. NEWS at 5302-03.

in or on a specified kind of food rather than emphasizing regulation of the industry or those persons who might use the substance. Since the major purpose underlying both amendments was to establish a procedure for pre-marketing clearance and to shift the burden of pretesting and proving safety from the government to those who propose to use such substances in food,¹³⁰ it can be argued that, at least in the context of environmental contamination, where the distributor of the product is not in a position to control, pretest, or solicit or receive approval for the use of these substances, the *per se* adulteration standards of the pesticide and food additive amendments should not be applied and the safety of the substance in a food should be considered on a more episodic basis.

The experiences with federal food law throughout this century have demonstrated that the forced application of an existing regulatory structure upon an unforeseen and unique factual situation ordinarily does not result in the most effective or realistic balance reconciling both the needs of the public and the requirements of the food industry. Although in the abstract the language of the FDCA is certainly flexible enough to cover almost any factual problem involving harmful, potentially harmful, or any other type of food component, it is questionable whether it makes sense to treat every new set of circumstances under the existing set of solutions.

The FDA has traditionally responded to these complexities by making extensive use of administrative lawmaking, often going to great lengths to substantiate its sometimes contrived interpretations of the statutory language and of the agency's powers.¹³¹ The current FDA policy appears to involve an initial attempt to classify all food substances under one of the separately regulated provisions of section 402 such as food additives or pesticides.¹³² If this categorization is for some reason not feasible or possible, any substance which is not an inherent natural constituent of a food will be treated as an added poison for which a tolerance for its use may

130. S. REP. No. 2422, *supra* note 51, at 2-3, [1958] U.S. CODE CONG. & AD. NEWS at 5301-02.

131. See Department of HEW, Notice of Proposed Rulemaking on Poisonous or Deleterious Substances in Food, 39 Fed. Reg. 42,743 (1974), which argues for the liberal interpretation of "added" in order that a tolerance level under § 406 could be established for all dangerous substances not occurring naturally in food. See generally 21 C.F.R. Part 109 (1980).

132. See, e.g., 21 C.F.R. Part 109 (1980).

be established under section 406.¹³³ Presently, the only official tolerance which has been promulgated under this section relates to levels which will be considered acceptable for residues of PCBs (polychlorinated biphenyls),¹³⁴ a deadly chemical sometimes found in food as a result of migration from machines employed during processing or from food packaging materials. PCB's have therefore been classified as incidental additives,¹³⁵ but since the chemical is a proven carcinogen, its presence or use in food, although mostly unavoidable, cannot be sanctioned under the food additive provisions.¹³⁶ The FDA, therefore, has made the factor of unavoidability the talisman for triggering the agency's tolerance setting authority under section 406,¹³⁷ whether or not the questioned substance is excluded from the added poison category because it falls within another specifically enumerated and separately regulated class of substances in the FDCA, such as food additives.

In view of the liberal construction given by the agency to the term "added poison," an incredible number and range in types of food components have become the subject of FDA extralegal "interim guidelines,"¹³⁸ which enumerate the level above which the presence of such substances in a food will cause the FDA to have a food seized or condemned. In many instances, such as is the case with PCBs and DDT, were it not for these unofficial tolerance levels several foods would be rendered adulterated as a matter of law due to their containing unsafe food additives or pesticides for which tolerances have not or cannot be established under the applicable provisions of the FDCA. However, the question raised by the present FDA approach toward regulation of substances in food is not whether such an approach is a useful or even a necessary one, but whether the agency's extralegal policies and lawmaking are consistent with those intended, allowed, or desired by Congress.¹³⁹

133. *Id.* Part 109.6.

134. *Id.* § 109.30 (1980).

135. *Nadick Paperboard Co. v. Weinberger*, 525 F.2d 1103, 1106-07 (1st Cir. 1975), *cert. denied*, 429 U.S. 819 (1976).

136. See FDCA § 409(c)(3)(A), 21 U.S.C. § 348(c)(3)(A) (1976).

137. 21 C.F.R. § 109.7 (1980).

138. Informal action levels have been established for such substances as aflatoxin, aldrin and dieldrin, cadmium, and lead in poultry, mirex, lindane, and paralytic shellfish toxin. See [1980] 3 FOOD DRUG COS. L. REP. (CCH) ¶ 50,280.

139. The FDA's policy of establishing informal tolerances has come under attack in recent years. In *United States v. Boston Farm Center, Inc.*, 590 F.2d 149 (5th Cir. 1979), for

In the context of mariculture, the present statutory scheme and judicial and administrative interpretations make it certain that all components of the mariculture process will be regulated under the pertinent specific sections of the FDCA as either food additives, pesticides on raw commodities, or new animal drugs. Mariculture, by definition, involves human attempts to simulate one of nature's processes, and thus every substance added, intended to be added, or incidentally added to the process would meet the statutory meaning of a food additive unless the ingredient is either generally recognized among experts as safe for its intended purpose, or unless it is a substance otherwise excluded, such as a pesticide, a new animal drug, or a previously sanctioned substance which would result only in the imposition of another similar regulatory scheme. If for some reason an ingredient of the mariculture process cannot be approved as safe for its intended purpose as a food additive, pesticide on a raw commodity, or new animal drug, and if the ingredient is required or is unavoidable in processing, then current FDA policies and interpretations of the FDCA may allow for the establishment of a tolerance under the added poisons provisions so that the use of the substance in production of the seafood could be permitted at the specified levels. All accidental poisons which become a component of the end product of the mariculture process will also be regulated under section 402(a)(2)(A) and section 406 as added poisons.

IV. GENERAL RECOGNITION OF SAFETY

The Food Additives Amendments of 1958 define food additives to exclude substances which are generally recognized as safe among experts qualified by scientific training and experience to evaluate their safety, or that have been adequately shown through

example, the court said that, with regard to informal guidelines on aflatoxin, the courts had given the agency considerable deference. The court continued:

The deference principle is less compelling when the agency threshold is a matter of prosecutorial discretion instead of rule-making. Congress requires considerably more fact-finding due process, most especially full notice and comment, in agency rule-making than in agency prosecutorial discretion. . . . The purposes of accuracy and fairness require that the courts not slavishly defer to the agency's in house prosecutorial guidelines arrived at without benefit of even minimal due process protections. At the extreme, the deference argument in this context sets up the blocking for an end run by the agency of the procedural checks in the statute for formal rule-making.

Id. at 151.

scientific procedures to be safe under the conditions of intended use.¹⁴⁰ In the case of substances used in food prior to January 1, 1958, general recognition of safety may be shown either through scientific procedures or experience based on common use in food.¹⁴¹

"Safe" means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use. Clearly, in the present state of scientific knowledge it is impossible to establish with complete certainty the absolute harmlessness of any substance. While safety may be determined by scientific procedures or by general recognition of safety, factors to be considered include the probable consumption of the substance and any substance formed in or on food because of its use, the cumulative effect of the substance in the diet (taking into account any chemically or pharmacologically related substance in the diet), and safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of food and food ingredients, are generally recognized as appropriate.¹⁴²

General recognition of safety may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food. Such recognition based upon scientific procedures requires the same quantity and quality of scientific evidence as required to obtain approval of a food additive. Further, general recognition of safety through scientific procedure ordinarily must be based on published studies which may be corroborated by unpublished studies and other data or information.¹⁴³

For a consideration of proof problems in the ascertainment of general recognition of safety, *United States v. 41 Cases, More or Less*¹⁴⁴ is helpful. The issue involved the general recognition of safety of a medicated poultry feed. Four university scientists, each of whom testified that he kept abreast of veterinary pathology through professional meetings, colloquia, and constant review of the literature, testified that a particular combination of chemicals at issue was not generally recognized as having been shown to be

140. FDCA § 201(s), 21 U.S.C. § 321(s) (1976).

141. *Id.*, 21 U.S.C. § 321(s).

142. 21 C.F.R. § 170.3(i) (1980).

143. *Id.* § 170.30(a)-(d).

144. 420 F.2d 1126 (5th Cir. 1970).

safe, since the available scientific literature was silent on the ingredients involved.¹⁴⁵ Furthermore, even if the government's expert witnesses were not qualified to judge the safety of the product, they could testify about the product's general recognition as safe or unsafe because the lack of literature establishing safety was proof that the product was not safe.¹⁴⁶ Another approach is illustrated by *United States v. An Article of Drug*.¹⁴⁷ The court said that

where there is a genuine difference of medical opinion among the experts on the question of whether a drug is generally recognized as safe for the treatment of a particular disease, it must be concluded that the drug is not generally recognized as safe for use in the treatment of that disease.¹⁴⁸

Substances used in food prior to January 1, 1958, may be evaluated either by scientific procedures or through experience based on common use in food. General recognition of safety acquired in the latter manner requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food. Such recognition may be determined without the quantity or quality of scientific procedures required for approval of a food additive regulation. However, such recognition must ordinarily be based upon generally available data and information. An ingredient not in common use in food prior to January 1, 1958, may achieve general recognition of safety only through scientific procedures.¹⁴⁹

The FDA has promulgated a list of substances which are generally regarded as safe for use in human food¹⁵⁰ and animal feed.¹⁵¹

145. *Id.* at 1130.

146. *Id.*

147. 294 F. Supp. 1307 (N.D. Ga. 1968), *aff'd*, 415 F.2d 390 (5th Cir. 1969).

148. *Id.* at 1311. *See also* *United States v. 354 Bulk Cartons Trim Reducing Aid Cigarettes*, 178 F. Supp. 847 (D.N.J. 1959); *Merritt v. Folsom*, 165 F. Supp. 148, 421 (D.D.C. 1958). *But see* *United States v. 7 Cartons, More or Less, Ferro-Lac Swine Formula Concentrate*, 293 F. Supp. 660 (S.D. Ill. 1968), *modified*, 424 F.2d 1364 (7th Cir. 1970). In *7 Cartons* the district court stated that the ruling in *Merritt* would equate the statutory language "generally recognized" to "unanimously recognized." Furthermore, the court said that there was nothing in the statute to indicate that Congress intended "generally recognized" to mean anything besides its commonly understood meaning, and that genuine differences of expert opinion does not prove want of general recognition. 293 F. Supp. at 662-63. This portion of the opinion was modified by the Court of Appeals for the Seventh Circuit on the ground that the holding was unnecessary, and therefore it had no precedential value. 424 F.2d at 1365. The reasoning of the district court, however, seems worthy of consideration.

149. 21 C.F.R. § 170.30(a) (1980).

150. *See id.* Part 182.

Clearly, it is not possible to list all substances that are generally recognized as safe for their intended use. Thus, a food ingredient of natural biological origin that has been widely consumed for its nutrient properties in the United States prior to January 1, 1958, without known detrimental effects and for which no known safety hazard exists, will ordinarily be regarded as generally recognized as safe without specific inclusion on the list.¹⁵²

Substances which are listed as generally recognized as safe (GRAS) are categorized as multi-purpose GRAS food substances,¹⁵³ anticaking agents,¹⁵⁴ chemical preservatives,¹⁵⁵ emulsifying agents,¹⁵⁶ nutrients and/or dietary supplements,¹⁵⁷ sequestrants,¹⁵⁸ or stabilizers.¹⁵⁹ When a substance is used for the purpose indicated, it is generally recognized as safe if it is used in accordance with good manufacturing practice. To so qualify, the quantity of substance added to food must not exceed the "amount reasonably required to accomplish its intended physical, nutritional, or other technical effect in food."¹⁶⁰ If a substance that is generally recognized as safe becomes a component of the food because it is used in manufacturing, processing, or packaging, the substance must be reduced as much as is reasonably possible if the substance serves no physical or technical purpose.¹⁶¹ The substance must be of an appropriate food grade and prepared and handled as the food ingredient.¹⁶²

A. Affirmation of GRAS Status

In 1969, the Food and Drug Administration began a reevaluation of the safety of substances generally recognized as safe for use in food.¹⁶³ A review leading to an affirmation of generally recog-

151. See *id.* Part 582.

152. *Id.* § 170.30(d).

153. *Id.* Part 182(B).

154. *Id.* Part 182(C).

155. *Id.* Part 182(D).

156. *Id.* Part 182(E).

157. *Id.* Part 182(F).

158. *Id.* Part 182(G).

159. *Id.* Part 182(H).

160. *Id.* § 182.1(b)(1).

161. *Id.* § 182.1(b)(2).

162. *Id.* § 182.1(b)(3).

163. See Graham, *Review on the 1970 NAS GRAS Pilot Survey (Phase I) and the 1971 NAS Comprehensive Survey (Phase II)*, 31 FOOD DRUG COSM. L.J. 26 (1976).

nized as safe status may be initiated by either the commissioner or the petition of an interested person.¹⁶⁴ A food ingredient affirmed as generally recognized as safe must, in addition to all the requirements in the applicable regulation, also be a food grade specification, perform an appropriate function in the food in which it is used, and be used at a level no higher than necessary to achieve its intended purpose.¹⁶⁵ If a substance is affirmed as generally recognized as safe with no limitation other than good manufacturing

164. 21 C.F.R. § 170.35(a) (1980). For human food, a petition for affirmation of GRAS status must include:

- (i) Description of the substance, including:
 - (a) Common or usual name.
 - (b) Chemical name.
 - (c) Chemical Abstract Service (CAS) registry number.
 - (d) Empirical formula.
 - (e) Structural formula.
 - (f) Specifications for food grade material, including arsenic and heavy metals. . . .
 - (g) Quantitative compositions.
 - (h) Manufacturing process (excluding any trade secrets).
- (ii) Use of the substance, including:
 - (a) Date when use began.
 - (b) Information and reports or other data on past uses in food.
 - (c) Foods in which used, and levels of use in such foods, and for what purposes.
- (iii) Methods of detecting the substance in food, including:
 - (a) References to qualitative and quantitative methods for determining the substance(s) in food, including the type of analytical procedures used.
 - (b) Sensitivity and reproducibility of such method(s).
- (iv) Information to establish the safety and functionality of the substance in food. Published scientific literature, evidence that the substance is identical to a GRAS counterpart of natural biological origin, and other data may be submitted to support safety. Any adverse information or consumer complaints shall be included. Complete bibliographic references shall be provided where a copy of the article is not provided.

(v) A statement signed by the person responsible for the petition that to the best of his knowledge it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him pertinent to the evaluation of the safety and functionality of the substance.

(vi) If nonclinical laboratory studies are involved, additional information and data submitted in support of filed petitions shall include, with respect to each nonclinical study, either a statement that the study was conducted in compliance with the requirements set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a statement that describes in detail all differences between the practices used in the study and those required in the regulations.

Id. § 170.35(c)(1) (1980). For GRAS affirmation of animal feed, see *id.* § 570.35.

165. *Id.* § 170.30(i).

practice, it is regarded as generally recognized as safe if the conditions of its use are not significantly different than those reported in the regulation as the basis on which the GRAS status of the substance was affirmed. This may be of particular significance in the mariculture context since, as the industry is a new one, it is highly unlikely that conditions of use of any new ingredient will be the same as those upon which affirmation of GRAS status was obtained. In such a case, a manufacturer may not rely on the regulation as authorizing the use but must independently establish that the use is generally recognized as safe or must use the substance in accordance with a food additive regulation.¹⁶⁶ A food ingredient may be affirmed within specific limitations, such as the type of food with which the ingredient can be used, the functional use of the ingredient, and the level of use. The affirmed ingredient can be used only within such guidelines.¹⁶⁷

The FDA is in the process of reviewing several categories of ingredients for GRAS affirmation.¹⁶⁸ First, it is studying naturally occurring substances which have been widely consumed without known detrimental effects but which have been significantly altered either by commercial procedures or by breeding or selection since 1958. The FDA is also reviewing distillates, isolates, extracts, and concentrations of extracts of GRAS substances; reaction products of GRAS substances; substances not naturally occurring but which are apparently identical to a GRAS counterpart of natural origin; and naturally occurring substances not intended for consumption for their nutrient properties.¹⁶⁹

B. Procedural and Substantive Standards for Administrative Determination of Safety of Separately Regulated Ingredients Under the FDCA

According to FDCA subsection 402(a)(2)(C), the presence of an unsafe food additive will render a food adulterated as a matter

166. *Id.*

167. *Id.* § 170.30(j). An affirmation process also exists for indirect food substances. This procedure does not authorize addition to any food ingredient, but rather authorizes use of its ingredient as indirect ingredient of food through migration from their immediate wrapper, container, or other food contact surface. *See id.* Part 186. This avenue is not pursued herein since the edible portion of live oysters will not be wrapped or packaged, as the mariculture is now conceived.

168. *Id.* § 170.30(f).

169. *Id.*

of law.¹⁷⁰ Under FDCA section 409, a food additive is unsafe if the substance and its proposed use do not conform to a regulation prescribing the conditions under which the substance can be safely used or if it has not received an exemption for investigational use.¹⁷¹ A regulation for a particular substance which is a food additive in accordance with the statutory definition or for a particular use may be issued upon the initiative of the FDA or by the agency in response to the petition of a person who wishes to manufacture or incorporate the substance into food which will be marketed in interstate commerce. The burden of testing and demonstrating the safety of unproven substances or uses of substances added to food is upon those who wish to use such substances in their products.¹⁷²

The food additive petitioner is required by section 409 to furnish the FDA with all relevant data pertinent to a determination of the safety of the substance in accordance with its proposed use.¹⁷³ After the statutory period allowed for an agency review of the petition,¹⁷⁴ the FDA must either issue a regulation setting out the conditions under which the additive can be used or deny the petition with notification of the reasons for the agency's action.¹⁷⁵

170. FDCA § 402, 21 U.S.C. § 342 (1976).

171. FDCA § 409(i), as currently codified, states:

Without regard to subsection (b) to (h); inclusive of this section, the Secretary shall by regulation provide for exempting from the requirements of this section any food additive, and any food bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health.

Id. § 409(i), 21 U.S.C. § 348(i).

172. *Id.* § 409(b), 21 U.S.C. § 348(b).

173. *Id.*

174. FDCA § 409(c)(2), as currently codified, provides:

(2) The order required by paragraph (1)(A) or (B) of this subsection shall be issued within ninety days after the date of filing of the petition, except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition.

Id. § 409(c)(2), 21 U.S.C. § 348(c)(2).

175. FDCA § 409(c)(1)(A)-(B), as codified, states:

(1) The Secretary shall—

(A) by order establish a regulation (whether or not in accord with that proposed by the petitioner) prescribing, with respect to one or more proposed users of the food additive involved, the conditions under which such additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or in which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any direc-

Any person who is adversely affected by an order issuing or denying to issue a regulation on a food additive may file an objection with the FDA and can request a public hearing to introduce evidence regarding the objection.¹⁷⁶ After a final order has been issued by the FDA subsequent to a public hearing, an aggrieved person may file a petition for judicial review of the agency's action.¹⁷⁷

The criteria which the FDCA requires that the FDA consider in deciding on the safety of a food additive include the probable consumption of the additive and its cumulative effect in the diet of humans or other animals, the effects of any related substances, and any other safety-related criteria deemed significant by recognized experts on the basis of animal experimentation.¹⁷⁸ Although the FDCA does not specify the degree to which a substance or its use must be proven safe for ingestion by humans or other animals, the legislative history indicates that proof of a "reasonable certainty that no harm will result" is the standard by which safety of food additive use will be measured.¹⁷⁹ The Senate Report on the Food Additive Amendments also provides that the indirect effect of an additive in a food which has been derived from another food to which the questioned substance was directly added should be considered by the FDA in evaluating whether the substance is safe as used.¹⁸⁰

tions of other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use), and shall notify the petitioner of such order and the reasons for such action; or

(B) by order deny the petition, and shall notify the petitioner of such order and the reasons for such action.

Id. § 409(c)(1)(A)-(B), 21 U.S.C. § 348(c)(1)(A)-(B).

176. FDCA § 409(f)(1), as currently codified, provides:

(1) Within thirty days after publication of an order made pursuant to subsection (c) or (d) of this section, any person adversely affected by such an order may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections. The Secretary shall, after due notice, as promptly as possible hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public.

Id. § 409(f)(1), 21 U.S.C. § 348(f)(1).

177. *Id.* § 409(g), 21 U.S.C. § 348(g). Those substances which have been the subject of an FDA regulation as food additives may be found at 21 C.F.R. §§ 172-180 (1980).

178. *Id.* § 409(c)(5), 21 U.S.C. § 348(c)(5) (1976); 21 C.F.R. § 170 (1980).

179. H.R. REP. NO. 2284, 85th Cong., 2d Sess. 5 (1958); S. REP. NO. 2422, *supra* note 51, at 6, [1958] U.S. CODE CONG. & AD. NEWS at 5305.

180. S. REP. NO. 2422, *supra* note 51 at 6-7, [1958] U.S. CODE CONG. & AD. NEWS at

The Delaney Clause to section 409 prohibits the FDA from finding that a food additive is safe for any intended purpose if, after testing, the additive is found to induce cancer in humans or other animals. One exception to the Delaney Clause, added to subsection 409(c)(3) in 1972, permits the FDA to approve the use of such substances in animal feed as long as no adverse effects on the animal will likely result and as long as no residues of the substances will be found in any edible portion of the animal once slaughtered or in any food derived from the animal while alive.¹⁸¹

The FDA's administrative processes and criteria for determining the safety of new animal drugs are in relevant part the same as for food additives.¹⁸² If a substance is a new animal drug or an animal feed containing a new animal drug,¹⁸³ its use must be approved by the FDA prior to marketing. Certain antibiotic drugs must, however, be certified in batches as having all of the characteristics of strength, quality, and purity upon the basis of which the animal drug application for that particular substance was approved.¹⁸⁴

The responsibility for regulation of the use of pesticides on raw agricultural commodities under the FDA is delegated to the Administrator of the Environmental Protection Agency (EPA).¹⁸⁵ A pesticide is defined under section 201(q) of the FDCA as any chemical which is a "pesticide" in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).¹⁸⁶ Any chemical which is intended to be incorporated into a pesticide compound is also subject to the procedural requirements of the FDCA and FIFRA.¹⁸⁷

According to section 408 of the FDCA, a pesticide chemical is unsafe and its presence on a raw agricultural commodity will cause that food to be adulterated under section 402 unless the chemical is generally recognized by experts as safe; it is used in accordance with an established tolerance; or if an exemption from the tolerance requirement has been met. Before a tolerance may be granted, the EPA must certify that the chemical is useful for its

5305.

181. FDCA § 409(c)(3), 21 U.S.C. § 348(c)(3) (1976).

182. *Id.* § 512, 21 U.S.C. § 360b; 21 C.F.R. §§ 510-582 (1980).

183. FDCA § 201(w), (x), 21 U.S.C. § 321(w), (x) (1976).

184. *Id.* § 512(n)(1)-(3), 21 U.S.C. § 360(n)(1)-(3).

185. *Id.* § 408, 21 U.S.C. § 346(a); 40 C.F.R. § 180.1 (1979).

186. 7 U.S.C. § 136 (1976 & Supp. III 1979).

187. FDCA § 201(q), 21 U.S.C. § 321(q) (1976).

intended purpose.¹⁸⁸

Although the EPA is the agency responsible for approving or denying approval of the use of pesticides on raw agricultural commodities, the FDA is responsible for enforcement of these provisions of the FDCA. In addition, tolerances for pesticides on processed foods when a chemical itself has not been the subject of a tolerance level, or when the presence of the chemical on a processed food exceeds the tolerance established for the raw item, are administered by the FDA.¹⁸⁹

C. Substances Added in Mariculture

Since mariculture involves two distinct food processes—the production of algae used to feed oysters and the production of seafood intended for human consumption—it is necessary to analyze the two processes separately under the regulatory scheme of the FDCA. The Act, however, does not distinguish between human and animal food in its definition of either the term “food” or the term “food additive.” Thus, the procedure for determining when a substance is a food additive under the legislation is the same whether the substance is a component of human or animal food. The “animal feed” category, as defined by section 201(x), was adopted along with the animal drug amendments, and its application is expressly limited to those instances when food for animals other than humans contains a new animal drug as defined by section 201(w).¹⁹⁰ In that situation, the animal feed bearing the new animal drug is regulated under the new animal drug provisions of section 512 rather than under section 409’s food additives provisions.

Two other consequences of classifying a food as either animal or human should be noted. First, the FDA, apparently for purposes of simplification, has segregated the animal food sections from the human food sections in the Code of Federal Regulations.¹⁹¹ Second, the substantive criteria for FDA approval of animal foods and food substances is somewhat more liberal than for human foods. For example, according to the Delaney Clause, food additives that are possibly carcinogens may be approved for inclusion in animal

188. 40 C.F.R. § 180.4 (1979).

189. 21 C.F.R. § 170.19 (1980).

190. FDCA § 201(x), 21 U.S.C. § 321(x) (1976).

191. 21 C.F.R. §§ 100-197 (humans), 500-582 (animals) (1980).

food as long as no trace of the cancer-causing substance will remain in any portion of the animal intended for human consumption.¹⁹² Other than these differences, the application and analysis of the FDCA to both human and animal food is the same.

The medium in which both the oysters and algae grow is seawater to which other substances are added. Under the definition of a food additive,¹⁹³ it seems that the sea water itself may be considered a food additive and regulated as such unless seawater is generally recognized as safe.

If sea water were composed of tap water and table salt an answer would be at hand. However, elements present in solution in sea water seem to run the gamut of the Periodic Table.¹⁹⁴ Further, the precise composition of seawater and the relationship of the elements therein one to another not only as yet defies precise analysis, but also is a function of the time at which the sample was collected. Further complicating the problem is the fact that the precise way the elements react together, and the compositions thus formed, is also unknown. Therefore, any attempt to assess the element present in seawater individually for purposes of determining their food additive or GRAS status is simply impossible. On the other hand, if sea water is treated as a substance in and of itself, rather than on a component by component basis, the analysis becomes simpler. The use of seawater in the mariculture process may avoid the pitfalls of a food additive determination if it, as a unitary substance, is generally recognized as safe. To so qualify, a substance must be recognized among experts qualified by scientific training and experience to evaluate their safety, or the substance must have been adequately shown through scientific procedures to be safe under the conditions of its intended use.¹⁹⁵ While it may not be possible to show a general recognition of safety through scientific procedure resulting in a published study in the case of seawater used for mariculture, it may be that general recognition of safety can be shown by experience based on common use in food,

192. FDCA § 409(c)(3)(A), 21 U.S.C. § 348(c)(3)(A) (1976)

193. "The term 'food additive' means any substance the intended use of which results . . . in its becoming a component or otherwise affecting the characteristics of any food." *Id.* § 201(a), 21 U.S.C. § 321(a).

194. See H. SVERDRUP, M. JOHNSON, & R. FLEMING, *THE OCEANS: THEIR PHYSICS, CHEMISTRY, AND GENERAL BIOLOGY* 176-77 (1970).

195. FDCA § 201(s), 21 U.S.C. § 321(s) (1976).

since seawater was used in the growing of oysters prior to January 1, 1958.¹⁹⁶

It must be kept in mind, however, that the categorization of seawater as generally recognized as safe for its intended use, or as a possible food additive status, depends on the willingness of the FDA to consider seawater as one substance and not require an element by element and compound by compound approach.

Two species of algae are currently grown as the primary oyster feed and, along with the seawater and other added ingredients, are introduced into the oyster's habitat, thereby qualifying them as food additives unless one of the exceptions is met.¹⁹⁷ At present, the two species being utilized are *Thalassiosira pseudonava*, a diatom, and *Isocirysis affgalbana*, a flagellate. Although some other species are generally recognized as safe for other uses,¹⁹⁸ these two species are neither approved as food additives nor listed as generally recognized as safe. Like seawater, however, they may be generally recognized as safe if recognized among experts qualified to evaluate their safety or have been shown through scientific procedures to be safe under their conditions of intended use. As these organisms form the diet of oysters both in mariculture and in their natural environment, and are certainly necessary for the oyster's survival, it seems likely that general recognition of safety can be shown if challenged. Furthermore, like seawater, it may be that since these organisms formed the diet of oysters prior to January 1, 1958, general recognition of safety may be shown by experience based on common use in food.

The substances added to the seawater and algae¹⁹⁹ may be considered individually for approval either as food additives or substances generally recognized as safe. However, it should be noted that while the food and drug laws and regulations speak in terms of what the substance is when it is introduced, no one knows even how the ionic forms of elements naturally present in seawater combine, much less what combinations result when outside substances, trace metals, and the like are added to a seawater medium. Given the present state of knowledge, the best that can be

196. See *id.*, 21 U.S.C. § 321(s).

197. *Id.*, 21 U.S.C. § 321(s).

198. See 21 C.F.R. § 182.40 (1980) (dealing with natural extractives used in conjunction with spices, seasonings, and flavoring).

199. Refer to Appendix.

done is to assess the status of each of the added ingredients individually.

The trace metals ferric chloride and disodium EDTA,²⁰⁰ and sodium nitrate and boric acid are approved as food additives, but only for very limited purposes. For example, disodium EDTA is approved for use for specific foods, for specific purposes, and in limited amounts.²⁰¹ Disodium EDTA is also approved for use in the manufacture of paper and paperboard²⁰² and in the manufacture of cellophane.²⁰³ Ferric chloride is also an approved food additive for use in food packaging,²⁰⁴ but apparently not for direct use in food for human consumption. The food additive sodium nitrate is permitted to be directly added to food for human consumption when used as a food preservative under specific conditions²⁰⁵ and also for use as a boiler water additive²⁰⁶ and in adhesives in food packaging.²⁰⁷ Sodium nitrate is neither generally recognized as safe or approved as a multi-purpose food additive, so it may not be used as an addition to food for human consumption other than under the conditions specified.

Boric acid is also neither generally recognized as safe or classified as a general purpose food additive, but rather is approved only for use in food package adhesives²⁰⁸ or for use in paper intended to come in contact with food.²⁰⁹ Sodium phosphate and sodium silicate are both approved as boiler water additives,²¹⁰ and sodium silicate is also approved as a food additive for use in the manufacture

200. Na₂ EDTA is disodium ethylenediaminetetra acetate, a buffer.

201. 21 C.F.R. § 172.135 (1980) prescribes the conditions under which Na₂ EDTA can be used and designates the foods in which it may be added for designated purposes. For example, the substance can be used alone as a preservative for mayonnaise or salad dressings, a cure accelerator for cooked sausage, to promote color retention in canned strawberry pie filling, or as a sequestrant for nonnutritive sweeteners. *Id.*

202. *See id.* § 176.150, which lists chelating agents which can be used to manufacture paper and paperboard.

203. According to federal regulations, cellophane may be used in food packaging, but there are limitations of the substances that can be used in the base sheet and coating. *Id.* § 177.1200.

204. *Id.* §§ 175.105 (adhesives), 176.170 (paperboard).

205. *See id.* § 172.170 for regulations concerning the use of sodium nitrate in foods as a preservative and color fixative. Since sodium nitrate is added to meat curing preparations for home curing, the regulation also provides that the label bear suitable directions to the consumer. *Id.*

206. *Id.* § 173.310.

207. *Id.* § 175.105.

208. *Id.*

209. *Id.* § 176.180.

210. *Id.* § 173.310.

of cellophane²¹¹ and for use in zinc silicon coatings.²¹² It should be noted, however, that sodium phosphate is also generally recognized as safe for general purpose use²¹³ and for use as a nutrient and/or dietary supplement.²¹⁴

Of the substances added to the phytoplankton nutrient media, several are generally recognized as safe. Of the vitamin group, vitamin B₁₂ is generally recognized as safe as a nutrient and/or dietary supplement when used in conformance with good manufacturing practice.²¹⁵ Biotin is similarly classified.²¹⁶ Thiamine is generally recognized as safe as a nutrient and/or dietary supplement in its hydrochloride²¹⁷ or mononitrate²¹⁸ forms. The trace metals zinc sulfate²¹⁹ and manganese chloride²²⁰ are also generally recognized as safe as nutrient and/or dietary supplements when used in conformity with good manufacturing practice. Sodium phosphate is classified as a generally recognized as safe substance,²²¹ and is also generally recognized as safe as a nutrient and/or dietary supplement when used in conformance with good manufacturing practice.²²²

211. *Id.* § 177.1200.

212. *Id.* § 175.390

213. *Id.* § 182.1778.

214. *Id.* § 182.5778. Refer to text accompanying notes 140-167 *supra* regarding GRAS status and its consequences.

215. 21 C.F.R. § 182.5945 (1980). "Good manufacturing practice" in this context means that:

(1) The quantity of a substance added to food does not exceed the amount reasonably required to accomplish its intended physical, nutritional, or other technical effect in food; and

(2) The quantity of a substance that becomes a component of food as a result of its use in the manufacturing, processing, or packaging of food, and which is not intended to accomplish any physical or other technical effect in the food itself, shall be reduced to the extent reasonably possible.

(3) The substance is of appropriate food grade and is prepared and handled as a food ingredient. Upon request the Commissioner will offer an opinion, based on specifications and intended use, as to whether or not a particular grade or lot of the substance is of suitable purity for use in food and would generally be regarded as safe for the purpose intended, by experts qualified to evaluate its safety.

Id., § 182.1(b).

216. *Id.* § 182.5159.

217. *Id.* § 182.5875. Thiamine HCl is now utilized in mariculture.

218. *Id.* § 182.5878.

219. *Id.* § 182.5997.

220. *Id.* § 182.5446.

221. *Id.* § 182.1778.

222. *Id.* § 182.5778. Sodium phosphate (NaH₂PO₄) also is approved as a boiler water additive. It may be used in the preparation of steam which will contact food under certain

The trace metals copper chloride, copper sulfate, and sodium malibidate added to the phytoplankton nutrient media are not listed as generally recognized as safe, nor are they approved for use as food additives for any purpose. Therefore, the use of these ingredients in the mariculture process would appear to require the ascertainment of generally recognized as safe or food additives status.

Ammonium chloride, which is sometimes used in place of sodium nitrate in the growing of *thalassiosira pseudonana*, is also nowhere approved for use. Tris, which is used in media for stock cultures, but not in mass culture for shellfish feed, also is unapproved.²²³

V. FILTHY OR UNFIT FOOD

Turning aside from substances added to the product produced, the Federal Food, Drug, and Cosmetic Act declares a food adulterated "if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food,"²²⁴ a circumstance mariculture attempts to prevent. The act does not provide for any tolerance for decomposition or filth, and if the statute were to be construed strictly, any evidence of mold and spoilage would be actionable. The de minimis principle generally has been applied where the amount in question was small,²²⁵ but not all courts have agreed with this approach.²²⁶

It has generally been held that if a food consists in whole or in part of filthy, decomposed, or putrid substances, its interstate shipment is prohibited whether it is otherwise considered as unfit for human consumption or not.²²⁷ In other words, even if a product is not unfit for food, it is adulterated if it contains a filthy, putrid, or decomposed substance. The product need not be injurious to

conditions, but this categorization is of no consequence in the mariculture context. *Id.* § 173.310.

223. Tris, used in the mariculture process, is trihydroxyaminomethane, a buffer. Other tris compounds have been approved for use in adhesive coatings intended for use in food packaging. *See id.* § 175.105.

224. FDCA § 402(a)(3), 21 U.S.C. § 342(a)(3) (1976).

225. *See United States v. 449 Cases Tomato Paste*, 212 F.2d 567, 575 (2d Cir. 1954).

226. *See id.*; *United States v. Tomato Paste*, [1980] 3 Food Drug Cos. L. Rep. (CCH) ¶ 50,057 (D. Mo. 1963).

227. *United States v. 1,851 Cartons Frozen Whiting*, 146 F.2d 760, 761 (10th Cir. 1945).

health.²²⁸ However, one case has expressed doubt concerning the correctness of the general view and suggested that the majority interpretation ignored the presence of the word "otherwise."²²⁹

The meaning of the word "filthy" in the context of seafood was a problem addressed early in the history of food and drug law. *United States v. Sprague*²³⁰ involved a criminal prosecution for the sale of ten barrels of oysters which were alleged to have been adulterated in that they "consisted in part of filthy, decomposed, and putrid animal and vegetable substance."²³¹ The oysters in question were unopened when taken from the waters of Rockaway, New York, and were placed into commerce in a living state without any manufacture or treatment. Nothing had been added except the ordinary water upon or in which the oysters lived. The complaint alleged that the oysters were adulterated because they contained bacteria, particularly the bacillus typhosus and other animal and vegetable bacilli, which were admittedly absorbed by the live oyster during its process of growth and from the liquid which it consumed in its natural function.²³² In overruling a demurrer by the defense, the court observed that it would hardly be open to argument that the words "filthy, decomposed, and putrefied" would be applicable to certain conditions resulting from the presence of living organisms since the conditions of animal substance known as filthy, decomposed, and putrefied are caused by the presence of such living organisms.²³³

Since living organisms begin to decompose immediately upon their death, the word "decomposed" in the Food and Drug law context means more than the beginning of decomposition and requires a state of decomposition.²³⁴ The amount of decomposition allowed and the methods for ascertaining it were discussed in *United States v. Ocean Perch Fillets*.²³⁵ There, quantities of ocean

228. See cases discussed in [1980] 3 FOOD DRUG COS. L. REP. (CCH) ¶ 50,057.

229. *United States v. 1,500 Cases More or Less, Tomato Paste*, 236 F.2d 208, 210-11 (7th Cir. 1956).

230. 208 F. 419 (E.D.N.Y. 1913) (construing the Food and Drug Act of 1906, ch. 3915, § 2 (repealed 1938)).

231. Note that the act lists the vices in the alternative while the charge in this case states the violations in the conjunctive.

232. 208 F. at 241.

233. *Id.*

234. *A.O. Andersen & Co. v. United States*, 284 F. 542 (9th Cir. 1922) (construing the Act of 1906, § 7 (repealed 1938)).

235. 196 F. Supp. 255 (D. Me. 1961).

perch, sometimes known as red fish, were seized by the Food and Drug Administration as constituting a decomposed substance within the statutory definition of adulterated food. It was undisputed that the quality control measures employed by the owner of the seized fish were above average, both in the operation of its trawlers and in the processing and packing of the fillets on its plant.²³⁶ The FDA had randomly selected packages of frozen ocean perch and a qualified FDA analyst made an organoleptic examination of the sample.²³⁷ The court noted that the organoleptic test by smell is accepted by the FDA and the fish industry both as a reliable method and the standard method for detecting a state of decomposition of frozen fish.²³⁸ Following classifications utilized by both the Food and Drug Administration and the fish industry,²³⁹ the court found that the lots of frozen fish involved contained in excess of ten percent class two fillets and in excess of six percent class three fillets, which extended throughout the entire lot. Holding a class three ocean perch fillet to be decomposed within the meaning of the act, the court found each lot to be adulterated because it consisted in part of a decomposed substance by reason of the presence therein of more than 6 percent class three fillets. The court thus found it unnecessary to consider whether the Food, Drug, and Cosmetic Act admits of a de minimis exception.²⁴⁰

As decomposition is a problem encountered with foods which are no longer living, it should not be a major consideration in a properly functioning closed cycle mariculture operation, as it is foreseen that the product of such an operation will be live animals.

The phrase "unfit for food" is not a restrictive one, but rather is additional or cumulative.²⁴¹ The unfit for food standard was construed in the seafood context in the case of *United States v. 24 Cases, More or Less*,²⁴² where it was claimed that the product was

236. *Id.* at 257.

237. *Id.*

238. *Id.* at 260.

239. Class 1 fillets have no odor, a slight stale odor, or a slight fishy odor which is characteristic of the species, but it is not offensive. Class 2 fillets emit a slight but distinct odor of decomposition which may dissipate on contact with air. Class 3 fillets have a strong odor of decomposition. *Id.* See also [1980] 3 FOOD DRUG COS. L. REP. ¶ 50,285.

240. See also *United States v. 1,851 Cartons Frozen Whiting*, 146 F.2d 760 (10th Cir. 1945), where approximately 6 percent of the contents of each 15-pound carton of frozen fish consisted of a decomposed substance, and the court held the food to be adulterated although the balance of the contents were fit for human consumption. *Id.* at 761.

241. *United States v. 449 Cases Containing Tomato Paste*, 212 F.2d 567 (2d Cir. 1954).

242. 87 F. Supp. 826 (D. Me. 1949).

unfit for food because of its "tough, rubbery consistency."²⁴³ The court noted that the interpretation of the word "adulterated" extends far beyond the dictionary meaning of the word, that is, a substance corrupted by the addition of a foreign substance, and noted several cases where food products that contained no filthy, putrid, or decomposed substances, nor any other harmful material, were condemned because they were characterized by an abnormal odor, taste, or color.²⁴⁴ It was the court's conclusion that a food product may conceivably be unfit for food by reason of an excessively tough or rubbery consistency, and admitted that the issue is solely a factual one.²⁴⁵ The court concluded that in order for a product to be subject to condemnation as unfit for food on account of its tough and rubbery consistency, the product must be proved to be so tough and rubbery that the average, normal person, under ordinary conditions, would not chew or swallow it.²⁴⁶

While there is no statutory provision for tolerances for filthy, putrid, or decomposed substances in food, the FDA has set "defect action levels" for many food defects.²⁴⁷ While the strict provision of the Food, Drug, and Cosmetic Act prohibits any amount of filth or decomposition, compliance with the defect action levels will usually avoid prosecution or seizure of food products.²⁴⁸

Food action defect levels reflect the level of use of an ingredient that would pose no hazard to human health. Even if the amount of the controlled ingredient does not exceed the action defect levels, however, the FDA can still take action against any food that poses any sort of health hazard.²⁴⁹ The action levels do not represent an average of the defects that occur in any of the food categories, but rather represent the limit at or above which the

243. *Id.* at 827.

244. *Id.*

245. *Id.* at 828.

246. *Id.*

247. See [1980] 3 FOOD DRUG COS. L. REP. (CCH) ¶ 50,280. The list of defect action levels is not itself a part of the FDA regulations and has never been published in the Federal Register. The defect action levels may be found in HEW document HFF 342, February 1978, or in the Food, Drug, and Cosmetic Law Reporter. *Id.* ¶¶ 50,060, 50,280.

248. *Id.* ¶ 50,060.

249. *Id.* ¶ 50,280. Note that failure to conform with GMP standards will result in regulatory action whether the product is below the defect level or not. *Id.* As the food processing industry is in a constant state of flux, practices which might have been acceptable in 1974 as current good manufacturing practices might be totally unacceptable in 1977. *United States v. General Foods Corp.*, 446 F. Supp. 704, 753 (N.D.N.Y.), *aff'd*, 591 F.2d 1332 (2d Cir. 1978).

FDA will take legal action against the product to remove it from the market. Thus, the averages are actually much lower.²⁵⁰ Unlike tolerances, defect action levels are by product rather than by substance, and no defect action levels for oysters yet exist.

The Food and Drug Administration is not statutorily required to establish defect action levels.²⁵¹ In the absence of a defect action level for a particular food, or a particular element of filth or decomposition, any measurable quantity is actionable. However, where no applicable defect action level is in effect and there is no evidence that the quantity of filth found in the food is avoidable through the use of good manufacturing practice, taking into account the state of the industry, small quantities of filth in food can be overlooked by our courts and no violation of the Act will be found under such circumstances. Despite these imprecise guidelines, however, the standards are not unconstitutionally vague.²⁵²

VI. GOOD MANUFACTURING PRACTICES

Early impetus for regulation of food plant conditions and sanitation arose in 1956 when a shipment of allegedly adulterated tomato paste was seized by the Food and Drug Administration.²⁵³ Although the FDA was able to show that conditions in and around the plant were less than satisfactory,²⁵⁴ the canner was able to convince the court that conditions and manufacturing practices in the plant were equivalent to conditions found in canneries throughout the country.²⁵⁵ The Food and Drug Administration was advised by the court of appeals that "if the Food and Drug Administration desires to improve the industry average, it would seem more likely to receive the support of the courts if it promulgated regulations which provided detailed standards as to cleaning procedures, screens, hygiene facilities, etc., publishing them to food packers as requisites for complying with subsection 402(a)(4), and then seiz-

250. [1980] 3 FOOD DRUG COS. L. REP. (CCH) ¶ 50,280.

251. *United States v. General Foods Corp.*, 446 F. Supp. 740, 745 (N.D.N.Y.), *aff'd*, 591 F.2d 1332 (2d Cir. 1978).

252. *Id.*

253. *See United States v. 1,500 Cases More or Less, Tomato Paste*, 236 F.2d 208 (7th Cir. 1956).

254. Although not conclusive, there was considerable evidence that an unsanitary labor camp was located close enough to the canning factory to affect the conditions under which the tomato paste was prepared. *Id.* at 212.

255. *Id.*

ing food packing plants not meeting the specific standards set.”²⁵⁶

Further, the extraordinary amount of food produced and processed in the United States makes analysis of food products cumbersome, and sampling gives rise to statistical difficulties. Therefore, analysis of food products cannot provide complete assurance that the product is free from contamination. Additional incentive to apply the drug good manufacturing philosophy to the food industry was provided in 1967 when manufacturing practice problems in the seafood industry threatened outbreaks of botulism food poisoning. The Food and Drug Administration responded with a two-step approach under which they first promulgated so-called umbrella regulations applicable to the entire food industry and then formulated a series of separate appendices for individual foods.

Subsection 402(a)(4) of the Food, Drug, and Cosmetic Act deems food to be adulterated if it has been “prepared, packed, or held under conditions whereby it may have become contaminated or injurious to health.”²⁵⁷ Pursuant to this section, the Food and Drug Administration promulgated the umbrella Good Manufacturing Practice (GMP) regulations for food, which first took effect on April 26, 1969.²⁵⁸ The Good Manufacturing Practice regulations require no showing of actual contamination of the finished product but relate only to the incipency of contamination.²⁵⁹ It is interesting to note that this concept is similar to that employed by the Clayton Act, where market structure, rather than actual market behavior, provides the only effective possibility of enforcement.²⁶⁰

The umbrella GMP regulations are replete with requirements which use terms such as “sufficient,” “minimize,” “adequate,” “appropriate,” and “proper.” While there can be no doubt that if no facilities for a particular operation are provided, there are no adequate facilities, it has been contended that words such as “adequate” provide a dynamic standard when they come to mean the very best which have been encountered by a particular FDA inves-

256. *Id.* Additional support for the concept of Good Manufacturing Practices came from Congress' enactment of the Kefauver-Harrison Amendment applicable to drugs in 1962. Kefauver-Harrison Amendment of 1962, Pub. L. No. 87-781, 76 Stat. 780 (codified in scattered sections of 21 U.S.C. §§ 301-392 (1976)). See Thompson, *Current GMP Regulations Applicable to the Human Food Industry*, FOOD DRUG COSM. L.J. 279 (1970).

257. FDCA § 402(a)(4), 21 U.S.C. § 342(a)(4) (1976).

258. Barnard, *Food GMP's*, 25 FOOD DRUG COSM. L.J. 123 (1970).

259. *Berger v. United States*, 200 F.2d 818, 821 (8th Cir. 1952).

260. Barnard, *Food GMP's*, 25 FOOD DRUG COSM. L.J. 123 (1970).

tigator to date.²⁶¹ On the other hand, in *Berger v. United States*,²⁶² a case which predated the GMP regulations and construed only the statutory language "prepared and packed under unsanitary conditions whereby it may have become contaminated with filth," a challenge to a criminal conviction based on vagueness was unsuccessful.²⁶³

Current GMP regulations also use terms such as "prevent," "eliminate," "no potential for," and "shall be kept free of." Such words and phrases appear to create absolute requirements, and, in theory, if a FDA inspector could find one insect in a warehouse, all of the warehouse's contents might be considered adulterated.²⁶⁴

It was once a question whether the current GMP regulations should reflect average or satisfactory existing conditions for the industry or whether they should be action-forcing, that is, stating desired levels not currently achieved within the industry.²⁶⁵ An examination of the current and proposed GMP regulations for the food industry leaves little doubt that the action-forcing approach has been adopted.²⁶⁶ The first two specific industry GMPs were proposed for the frozen shrimp industry in September 1969, and

261. Morey, *GMPs and GLPs—Where Are We Going*, 32 FOOD DRUG COSM. L.J. 459, 465 (1977).

262. 200 F.2d 818 (8th Cir. 1952).

263. *Id.* at 822. It seems possible that the court in *Berger* may have been influenced by the rather extreme facts of the case. *Berger* involved a pickle plant housed in a large brick building, which had 200 unscreened windows. The glass in 20 to 25 of those windows had broken out, allowing pigeons to fly in and out. Occasionally, the pigeons were shot and killed inside the plant. At the time of the inspection, no pickles were being canned, and the hopper of the pickle chopper was rusted and corroded, the shaft was rusted, and grease was running down the shaft onto the cutting blades. Pickle relish material remaining from the last operation was imbedded in cracks in the wooden trough. A wooden table in the relish-making area was covered with dust and stained material, and the supporting structure was encrusted with spider webs. Vinegar flies were flying over uncovered barrels, spider webbing partially covered the openings of six full barrels, and house flies rested on pickles in other barrels. Spiders, bird feathers, and dead flies in the pickle vats apparently were commonplace. Inspectors found decomposed pickles, sticks, grass, muddy pickles, and what appeared to be insects in the pickle vats. Although not germane to the issue of presumptive adulteration, analysis of the contents showed that the pickle jars contained fly fragments, mites, part of a beetle wing, a moth's scale, fragments of feathers, and rodent hair. *Id.* at 823-24.

264. Wittick, *Proposed Revisions of the Current GMP Regulations*, 32 FOOD DRUG COSM. L.J. 279, 283 (1977).

265. Thompson, *Current GMP Regulations Applicable to the Human Food Industry*, 25 FOOD DRUG COSM. L.J. (1970).

266. Other federal regulatory statutes have also adopted this philosophy. See, e.g., Clean Air Act, 42 U.S.C. §§ 7401-7642 (Supp. III 1979).

for the smoked fish industry the following month.²⁶⁷ Specific industry GMP regulations now exist for more than twenty food industries ranging from milk and cream, frozen deserts, and canned fruit juices, to shucked oysters and canned salmon.²⁶⁸ One regulation deals with fish and shellfish, but its scope is limited to shucked and canned oysters and deals primarily with size requirements and the water or saltwater with which the shucked oysters come in contact. Thus, a mariculture operation would be subject only to the umbrella Good Manufacturing Practice regulations applicable to the food industry as a whole, because the products are sold in the shell. Should any form of shucking, processing, or canning be added to the mariculture facility, such processes would be subject to the Good Manufacturing Practices applicable to shellfish, regardless of their origin.²⁶⁹

A. *Good Manufacturing Practices: Specific Provisions*

Good Manufacturing Practices regulations cover such food preparation areas as personnel requirements, the plants and grounds used in the manufacturing process, sanitary facilities and controls, sanitary operations, equipment and procedures, coding provisions, and recordkeeping. The regulations would be applicable to the mariculture process, but due to the unique nature of the product and process of mariculture, some of the requirements which seem to be applicable by their terms do not alleviate any threat to product quality.

Plant management is required to take all reasonable measures to assure that no person affected by a disease in communicable form, or a carrier of such disease, will be employed in a food manufacturing plant where there is a reasonable possibility of contamination of food ingredients.²⁷⁰ The regulations include standards for garments and personal cleanliness.²⁷¹ The proposed regulations are slightly more detailed but do not differ from existing regulations in any substantive manner that would be applicable to the maricul-

267. See generally Barnard, *Food GMPs*, 25 FOOD DRUG COSM. L.J. 123 (1970).

268. See 21 C.F.R. Parts 118-169 (1980).

269. In late 1979, the FDA proposed revisions to the umbrella GMP regulations and, while they have not been adopted, are noted herein. 44 Fed. Reg. 33,238, 33,243-48 (1979).

270. 21 C.F.R. § 110.10 (1980). Responsibility for assuring compliance with these requirements must be assigned to a competent supervisory person. *Id.* § 110.10(d).

271. *Id.* § 110.10(b). Employees who work directly with food preparation must wear clean outer garments and maintain high standards of personal cleanliness. *Id.*

ture situation.²⁷²

The plants and grounds used in the manufacturing and processing also are subject to current GMP regulations.²⁷³ The grounds and buildings must be clean and well-kept, with adequate lighting and ventilation. The buildings must be so constructed as to guard against insects, birds, or other animals. The proposed regulations also require that the management make efforts to reduce the potential contamination of end products, raw materials, or food packaging materials with micro-organisms, chemicals, filth, or other extraneous materials. The regulations suggest that the potential for contamination may be reduced by the separation of each step in the operation, such as food preparation and processing operations, packaging, and equipment maintenance.²⁷⁴ Similar requirements were adopted in the current GMP regulations for the candy industry, and the FDA advised that the use of partitions was only one method of separating operations and that other means are acceptable.²⁷⁵

Each plant must be equipped with adequate sanitary facilities, including adequate water supplies and sewage disposal,²⁷⁶ and each plant also must abide by regulations for sanitary operations.²⁷⁷ While the basic requirement is simply that buildings and other physical facilities be kept in good repair and maintained in a sanitary condition, the regulations also control such things as detergents, the use of insecticides, and equipment maintenance and cleaning.²⁷⁸ The proposed regulations note that poisonous or dangerous cleaning compounds and pesticide chemicals must be identified and used only in a manner and under conditions that will be safe for their intended use.²⁷⁹

The regulations dealing with equipment and procedures relate primarily to the use of polychlorinated biphenyls (PCBs) in food

272. See 44 Fed. Reg. 33,243 (1979).

273. 21 C.F.R. § 110.20 (1980).

274. *Id.* The grounds surrounding a plant must be free from conditions which may result in food contamination. *Id.* § 110.20(a). Plant buildings and structures must be suitable in size, construction, and design to facilitate maintenance and sanitary operations. The regulations give specific standards and guidelines for lighting, ventilation, separation of operations, and screening. *Id.* § 110.20(b).

275. 44 Fed. Reg. 44,240 (1979).

276. 21 C.F.R. § 110.35 (1980).

277. *Id.* § 110.37.

278. *Id.*

279. 44 Fed. Reg. 33,243 (1979) (to be codified in C.F.R. § 110.35(a)).

plants. New equipment, utensils, and machinery used to handle and process food may not contain PCBs.²⁸⁰ Existing equipment must be tested for PCBs, and if there is a reasonable likelihood that any PCB-containing equipment would cause food contamination, those items must be removed.²⁸¹ The new regulations relax PCB rules somewhat, although utensils should not contain PCBs. Also, the new regulations describe standards of cleanliness and maintenance, and require that food contact surfaces be free from corrosion. Temperature control equipment also must be accurate and effective.²⁸²

The GMP regulations require that overall plant sanitations be under the supervision of an individual assigned responsibility for that function.²⁸³ All foods and ingredients that have been contaminated must be rejected or treated to eliminate the contamination, and chemical, microbiological, or extraneous material testing procedures must be used when necessary to identify food contamination. Food processing must be conducted under such conditions and controls as are necessary to minimize the potential for undesirable bacterial or microbiological growth, toxin formation, or deterioration or contamination.²⁸⁴

Meaningful coding of products distributed from a manufacturing, processing, packing, or repacking activity should be utilized to enable positive lot identification. Since there were 163 recalls of food products in 1976,²⁸⁵ the FDA chose to emphasize the importance of the coding provisions by putting the applicable regulations in a new section.²⁸⁶ The new requirements mandate permanently legible code marks on each finished food package delivered or displayed to purchasers so that the code marks can be seen on the unopened package. The marks must identify at least the plant where the food was packed and the lot or packing lot.²⁸⁷

Records should be retained for a period of time that exceeds the shelf life of the product, except that the records need not be

280. 21 C.F.R. § 110.40(a)(1) (1980).

281. *Id.* § 110.40(a)(2). Tolerances for PCB's are found in 21 C.F.R. § 109.30 (1980).

282. 44 Fed. Reg. 33,243, 33,246 (1979) (to be codified in 21 C.F.R. § 110.40(i)).

283. 21 C.F.R. § 110.80 (1980).

284. *Id.*

285. 44 Fed. Reg. 33,241 (1979).

286. *Id.* at 33,248 (1979) (to be codified in 21 C.F.R. § 110.91).

287. *Id.* The coding provisions of the current GMP regulations for the candy industry have been upheld in *National Confectioners Ass'n v. Califano*, 569 F.2d 690, 695 (D.C. Cir. 1978).

kept for more than two years. Distribution records, processing and production records, and examination records are included under the regulations.²⁸⁸

It should not be difficult for one constructing a new plant for mariculture to meet the largely common-sense requirements of the umbrella good manufacturing practices. Adaption or conversion of older facilities, such as warehouses, may present minor difficulties, but should not deter potential mariculture entrepreneurs concerned with the quality of their products and their relations with the FDA.

VII. CONCLUSION

It is clear that the evolution of the food additive and related provisions of the Food, Drug, and Cosmetic Act tracked the progress of federal regulation in general rather than the progress of food technology. The patchwork of regulation seems able to function with respect to traditional food processors more because of the FDA's manipulative skills than its statutory artistry, and because of the relatively standardized ingredients of most processed foods. Clearly, however, new technology, particularly as illustrated by closed cycle mariculture, a process whose goal—safe food—is the same as the FDCA, is disadvantaged by the process and ingredient-oriented approach taken by and under the statute. Although it is impossible to document with certainty, the wide administrative discretion accorded the FDA and available informal dispute resolution mechanisms²⁸⁹ make it likely that the FDA will be able to accommodate a properly functioning closed cycle mariculture facility if it is inclined to do so.

The performance standard approach of GRAS status, the filthy, unfit, or decomposed substance provisions, and, to a lesser extent, the good manufacturing practices, are all of a sort which invite technological improvement and concentrate on result rather than process. Such an approach clearly favors new and advanced technology functioning properly.

While the Food, Drug, and Cosmetic Act does little to encourage technological advance, neither does it inhibit it in a conse-

288. See 21 C.F.R. § 110.80 (1980); 44 Fed. Reg. 33,243, 33,248 (1979) (to be codified in 21 C.F.R. § 110.100).

289. See, e.g., 21 C.F.R. § 10.85 (1980) (advisory opinions).

quential manner so long as the FDA policy includes interpretation consistent with the Act's purposes.

panding the child's expectation of liberty and the legal constraints still in operation.

The United Nations Convention on the Rights of the Child is a bold and innovative document, a consensus of international legal and political opinion concerning those rights which children ought to expect their national governments to recognize. However, a close examination of the language of the document reveals the tension still inherent in the area of children's rights between the control that parents, and to a lesser extent the State, maintain over children and the autonomy that children can claim through the rights recognized in this international agreement.

II. GENERAL WORKS ON HUMAN RIGHTS IN INTERNATIONAL LAW

A. *Treaties, Conventions, and Agreements*

Until the Convention was opened for signature, children's rights advocates funnelled claims for minors through other conventions and agreements such as the International Covenant on Civil and Political Rights;³ these agreements still serve as an alternate mechanism for the application and enforcement of children's rights as a subset of individual human rights. Many international agreements focus on human rights in international law, and by implication encompass protection of the child's rights under international law. The United Nations Charter, for example, states as one of its goals "[t]o reaffirm faith in fundamental human rights, in the dignity and worth of the human person, in the equal rights of men and women and of nations large and small."⁴ The Universal Declaration of Human Rights,⁵ which "reflects an international consensus on the basic rights of man and which signals the beginning of a struggle to create enforceable international norms"⁶ and subsequent declarations reiterate and amplify the rights presented in the U.N. Charter, but since they are nonbinding, their influence has been limited to generating binding international covenants⁷ such as the United Nations International Covenant on Civil and Political Rights,⁸ the International Covenant on

³ See e.g., Lysaght, *The Scope of Protocol II and Its Relation To Common Article 3 of the Geneva Conventions of 1949 and Other Human Rights Instruments*, 33 AM. U.L. REV. 9 (1983).

⁴ U.N. CHARTER preamble.

⁵ G.A. Res. 217A, U.N. Doc. A/810 at 71 (1948). B.G. RAMCHARAN, *THE CONCEPT AND PRESENT STATUS OF THE INTERNATIONAL PROTECTION OF HUMAN RIGHTS: FORTY YEARS AFTER THE UNIVERSAL DECLARATION* (1988), provides a learned study of the impact of the Universal Declaration and related covenants.

⁶ Eekelaar, *Parents and Children—Rights, Responsibilities and Needs: An English Perspective*, 2 HUM. RTS. ANN. 81, 112 (1984).

⁷ *Id.* at 113.

⁸ G.A. Res. 2200A, 21 U.N. GAOR Supp. (No. 16), at 49, U.N. Doc. A/6316 (1966). There is also an *Optional Protocol to the International Covenant*, G.A. Res. 2200, 21 U.N. GAOR Supp. (No. 16) at 59, U.N. Doc. A/6316 (1966). For a discussion of the meaning and operation of the Cove-